UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** **All Direct Purchaser Actions**	**Civil Action No.: 1:15-CV-07488-CM-RWL**

DIRECT PURCHASER CLASS PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

SUBMITTED FOR FILING UNDER SEAL

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ABBREVIATION	DESCRIPTION
Forest	Forest Laboratories, LLC, Forest Laboratories Holdings Limited, and Forest Laboratories, Inc.
Mylan	Mylan Pharmaceuticals, Inc.
Alphapharm	Alphapharm Pty, Limited
PASoF ¶__	Plaintiffs' Affirmative Statement of Material Facts in Opposition to Forest's Motion for Summary Judgment
PRSoF ¶__	Plaintiffs' Responses and Objections to Defendants' Statement of Undisputed Facts
DSoF ¶__	Defendants' Statement of [Alleged] Undisputed Facts
AG	authorized generic
Def. Br.	Defendants' Memorandum in Support of Their Motion for Summary Judgment

I. INTRODUCTION

Forest's summary judgment motion should be denied, as there is ample evidence for a jury to find that (1) the Amendment to Distribution and Supply Agreement (Generic Lexapro) (the "Lexapro Amendment") contained a large and unjustified reverse payment from Forest to Mylan; (2) but for the unlawful reverse payment, generic versions of Namenda would have entered the market much earlier and therefore the reverse payment caused Plaintiffs antitrust injury; and (3) Forest's unlawful product hop was a substantial factor in causing Plaintiffs antitrust injury.[1]

A. The Mylan Patent Settlement Contained an Unlawful Reverse Payment

The following facts are undisputed. [redacted] The evidence that the Lexapro Amendment and the Namenda patent settlement agreement are interconnected is overwhelming. [redacted] Mylan, the last of the 14 generic ANDA filers to settle the Namenda patent litigation, was a potential "spoiler" of Forest's delicate set of settlements with other ANDA filers. They were delicate, because each generic agreed to delay entry only for so long as the others did, and if one entered, then they all could. Thus, Mylan was paid far more than any other generic. [redacted]

In attempting to obtain summary judgment, Forest argues – as it must under the burden-shifting rule of reason and *Actavis* – that the [redacted] reverse payment was not for delay, but

[1] Plaintiffs are not pursuing their inter-generic conspiracy claim (Count 4 of Plaintiffs' First Amended Class Action Complaint, ECF No. 26).

is explained by the value of services and money Mylan allegedly promised to give back to Forest. But Forest's explanations are contrived, pretextual, and disputed, and no jury would be required to believe them. Under the rule of reason, Forest bears the burdens of production and proof on its explanations, and so summary judgment on this claim is doubly inappropriate.

Forest's first explanation. Forest's first explanation for its [redacted] payment is that [redacted] This "explanation" is nothing but an accounting artifice designed to make the [redacted] "disappear." For Forest's argument to convince a jury, Forest must *show* one thing and *overcome* another. Forest has to *show* that Mylan was initially unwilling to continue selling AG Lexapro for that second year, and only became willing to do so because of Forest's reverse payments. If, however, Mylan was *already* willing to sell AG Lexapro for a "second year," then those services cannot explain the payments. Yet, Forest has no evidence that Mylan was initially unwilling to continue to sell AG Lexapro for a second year. [redacted] Forest's argument is based on the *post-hoc* deposition testimony of one of its executives that *Forest* allegedly had concerns that Mylan would terminate the Distribution and Supply Agreement (Generic Lexapro) ("Original Lexapro Agreement") after one year. [redacted], that Forest ever discussed the issue internally, or that Forest and Mylan discussed the subject at all.

Forest also has to *overcome* the undisputed evidence that it was obvious in advance that there would not be any "second year" AG Lexapro royalties to offset the [redacted] reverse

payment because twelve other Lexapro generics were going to drive prices and Mylan's market share down close to nil after six months. [redacted]. Forest relies on self-serving forecasts it created (over a three-day period *after* Forest had already agreed to pay Mylan [redacted]), but even Forest's negotiator, David Solomon, dismissed the underlying assumptions as wrong when they were created. Moreover, Forest's projections are 180 degrees at odds with Mylan's contemporaneous projections of [redacted] in the second year, that render Forest's projections highly dubious.

Forest's second explanation. Forest's second explanation for its [redacted] reverse payment is a ploy to fabricate offsetting money in the form of [redacted] in reduced Medicaid rebates Forest would otherwise owe to the government on Forest's sales of its own *brand* Lexapro, by getting Mylan to agree to manufacture AG Lexapro. [redacted].

Second, the [redacted] of purported avoided rebate liability came from the U.S. Treasury, ***not from Mylan***; from Mylan's perspective, it does not reduce the value of the [redacted] payment at all. To say that the [redacted] in avoided rebate liability offsets the [redacted] reverse payment ignores the disconnect between (1) payor and payee, and (2) the reasons for the payment and the offset. An incidental offset from someone other than the payee is legally irrelevant under *F.T.C. v. Actavis, Inc.*, 133 S. Ct. 2223 (2013). Whether the payment was sufficient to induce Mylan to quit the patent fight can only be assessed from Mylan's perspective. [redacted].

[redacted].

Finally, even if Forest could convince a jury to offset the [redacted] by [redacted], a large, unexplained reverse payment still remains. In other words, Forest's sole fair valuation expert, Mr. Green, has submitted to the Court a fundamentally flawed opinion: if the jury rejects Mr. Green's first explanation (the "second year" argument, discussed above) then it will be required to find that Forest – which under controlling law bears the burden of proof in explaining and justifying its payments to Mylan – made a large reverse payment to Mylan.

Forest's other explanations. Forest has toyed with a potpourri of other explanations, including that it paid [redacted] But Mylan leveled the same PTE theory in the patent case. [redacted]

B. But-For the Unlawful Reverse Payment Agreement, Generic Versions of Namenda Would Have Entered the Market Much Earlier

As this Court previously held, "[w]hether the settlement agreements were anticompetitive or procompetitive will depend on *several factual questions that cannot be decided on summary judgment*." ECF No. 252 at 40 (emphasis added). Indeed, Forest's causation arguments are inherently embedded with disputed issues of material facts. Forest nevertheless argues that there

is insufficient evidence to support a verdict that generic entry would have occurred but-for Forest's anticompetitive conduct. Def. Br. at 39-50. Not so. First, Plaintiffs' economics expert, Harvard Professor Einer Elhauge, opines that absent an illegal reverse-payment settlement, it would have been in Forest and Mylan's economic interests to agree to a no-payment settlement with an earlier generic entry date. *Actavis* endorses this approach. *Actavis*, 133 S. Ct. at 2237 (the parties "may, as in other industries, settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior that point."). Numerous courts have endorsed the premise that "in constructi[ng] but-for world scenarios, there is a presumption of economical rationality." *United Food & Commercial Workers Local 1776 v. Teikoku Pharma USA*, No. 14-MD-02521-WHO, 2017 WL 5068533, at *24 n.42 (N.D. Cal. Nov. 3, 2017) ("*Lidoderm*"). Moreover, Prof. Elhauge's methodology of using a brand and generic's own profit projections and their own profit-maximizing behavior to model an alternative settlement, as *Actavis* describes – without a payment but with an earlier entry date – was recently approved in another reverse payment case. *Lidoderm*, 2017 WL 5068533, at *11-13, *30-32. While Forest and its experts may disagree with Professor Elhauge's opinions, the ultimate question is for a jury.

Second, Plaintiffs possess a wealth of expert, documentary, and testimonial evidence from which a reasonable jury could readily conclude that Mylan was likely to prevail on its invalidity and/or non-infringement defenses. As this Court previously observed, if Forest had "lost the litigation, the patent would have been declared invalid or not infringed and the Generic Competitors could have entered the market immediately." Litvin Decl. Ex. 355, *In re Namenda Direct Purchaser Antitrust Litig.*, No. 15 Civ. 7488 (CM), at 37 (May 23, 2017) (unredacted version) ("Estoppel Op.").

C. Forest's Unlawful Product-Hop Caused Plaintiffs' Antitrust Injury

Plaintiffs' proof of antitrust injury from Forest's hard-switch strategy (which does not require proof of earlier generic entry) rests in large part on Forest's own contemporaneous forecasts, communications and market analyses. Plaintiffs' evidence also includes the testimony of two accomplished economists, Dr. Russell Lamb and MIT Professor Dr. Ernst Berndt. Dr. Berndt is a widely-recognized scholar and economist with decades of experience studying pharmaceutical markets. Judge Sweet repeatedly credited him in enjoining Forest from withdrawing Namenda IR. Dr. Lamb is a widely respected economist with substantial experience in assessing injury to purchasers in antitrust cases, and who has been credited by multiple district courts in assessing classwide damages. *See, e.g.*, *In re Domestic Drywall Antitrust Litig.*, No. 13-MD-2437, 2017 WL 3623466, at *39-42 (E.D. Pa. Aug. 23, 2017). The evidence of injury here involves questions of fact and expert opinion that cannot be resolved on summary judgment.

Forest incorrectly attacks Plaintiffs for allegedly failing to account for Forest's "soft-switch" factors. Plaintiffs' evidence does account for "soft-switch" factors, and the analyses by Drs. Lamb and Berndt comport with Judge Sweet's findings – confirmed by Forest's own forecasts and documents – that (1) Forest expected its "soft-switch" efforts to yield only about [redacted] conversion from Namenda IR to XR, (2) [redacted] and (3) Forest achieved a conversion rate of over [redacted]. As this Court found in granting estoppel against Defendants (PRSoF ¶ 464):

> **Both Judge Sweet and the Second Circuit concluded that the result of the hard switch would be that a "significantly higher" number of patients would convert from Namenda IR to Namenda XR than if Forest had not attempted to pull Namenda IR from the market. . . .** Forest's own internal projections estimated that, using only soft-switch tactics, only [redacted] of Namenda IR patients would voluntarily switch to Namenda XR. Under a hard-switch strategy, that percentage [redacted]

> ***
> Importantly, Judge Sweet found that Forest's hard-switch tactics had already resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily. **At the time the preliminary injunction was entered, "*about* [redacted] *of existing patients* [had] converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR." . . . This is significantly more than the [redacted] that Forest had estimated would convert if only soft-switch tactics were employed.**

Defendants argue that Dr. Lamb's methodology does not fit a test they fabricated using out-of-context quotes from the Court's motion to dismiss order, which identified one way that Plaintiffs ***could*** prove injury. It did not mandate a sole method by which Plaintiffs ***must*** prove injury. Nor would the Court have had occasion to, as evidence of the extent of Forest's conduct was not before the Court (indeed, no evidence was before the Court on a motion to dismiss).

Finally, Defendants ignore copious evidence that the effects of Forest's repeated announcements of Namenda IR withdrawal were not cured by Judge Sweet's December 2014 injunction. First, Forest understood that once physicians began prescribing Namenda XR, they would likely continue to do so. As Forest put it: [redacted] And Forest had stopped manufacturing Namenda IR (before the injunction) [redacted] Second, after the injunction, Forest began a communications blitz announcing it was appealing, and stating it was "optimistic" the injunction would be overturned, which sowed fear and doubt about the continued availability of Namenda IR. Defendants incorrectly claim that Dr. Lamb calculates hop damages pre-dating Forest's February 2014 publicity campaign. But Dr. Lamb correctly observes that Forest both [redacted] and widely communicated about the withdrawal before February 2014.

While Defendants criticize Plaintiffs for not analyzing "patient" switching behavior, Plaintiffs and the proposed class are *direct purchasers*. Unlike patients or physicians, direct

purchasers serve large swaths of the market, buy based on market demand, and do not purchase based on particular physician preferences. Thus, as Forest converted prescriptions to Namenda XR, direct purchasers were forced to buy the product to meet overall market demand. If, as Forest concluded, its "soft switch" alone would result in just [redacted] of patients switching to XR, then (1) logically, the hard switch caused the additional post-hard switch demand; and (2) there is no need to identify or trace individualized patient switching decisions because the hard switch's impact is reflected in wholesalers' own increased Namenda XR purchases. Accordingly, Dr. Lamb analyzed wholesaler level IMS National Sales Perspective and manufacturer data at the wholesaler level to identify the effects of Forest's hard switch on direct purchasers. Dr. Lamb thus observed the actual rate of switching and compared it to Forest's own soft-switch-only market share projections.

II. STATEMENT OF FACTS

A. The Patent Settlement Agreement and the Lexapro Amendment

1. The Original Lexapro Agreement Between Mylan and Forest

Forest's reverse payment took the form of an amendment to a prior agreement covering [redacted] Forest and Alphapharm (later acquired by Mylan), entered into the Original Lexapro Agreement. DSoF ¶182. The patent on Lexapro, another billion-dollar Forest drug, did not expire until 2012, but was being challenged in 2005 by an ANDA first-filer, Ivax (later acquired by Teva). PASoF ¶217. [redacted].

The Original Lexapro Agreement thus appealed to Alphapharm because [redacted]

[redacted]. PASoF ¶218(e). [redacted] PASoF ¶218(g). Mylan acquired Alphapharm in 2007. DSoF ¶218.

2. The Lexapro Amendment

[redacted] PASoF ¶¶220-21. The Lexapro Amendment [redacted]. PASoF ¶221(b). Thus, compared to the Original Lexapro Agreement, the Lexapro Amendment [redacted] DSoF ¶243. [redacted]. PASoF ¶221(d). [redacted] PASoF ¶221(g). [redacted] PASoF ¶221(i).

3. Negotiations of the Patent Settlement and the Lexapro Amendment

The Namenda patent settlement agreement and the Lexapro Amendment were both signed on July 21, 2010. PASoF ¶239. This was no coincidence; the Lexapro Amendment was Mylan's payoff to quit the patent fight. Between the execution of the Original Lexapro Agreement in 2005 and the first discussions surrounding the settlement of the Namenda patent dispute between Mylan and Forest (in August of 2009), the parties had not revised the Original Lexapro Agreement at all. PASoF ¶225. It was not until after the August 2009 Namenda patent settlement discussions that

Forest raised with Mylan a possible amendment. PASoF ¶¶222-26.

The Lexapro Amendment was linked to the Namenda patent settlement. Prior to [redacted], Forest executives and lawyers gathered material, including documents entitled [redacted] PASoF ¶¶227-28. [redacted] PASoF ¶229. [redacted] PASoF ¶¶230-31. [redacted] PASoF ¶232.

The evidence and Defendants' own admissions demonstrate that Forest's David Solomon [redacted] each negotiated both the Lexapro Amendment and the Namenda patent settlement. PASoF ¶234. Any suggestion that the two agreements were "separate" is fatuous.

4. Forest Told Mylan That the Lexapro Amendment Offered [redacted] to Mylan, While There Was [redacted] for Mylan to Compete in the Namenda Market

Forest told Mylan that the Lexapro Amendment had more financial value to Mylan than a Mylan Namenda patent litigation victory and launch. In a February 11, 2010 Forest-Mylan settlement presentation, Forest detailed the [redacted] PASoF ¶235. [redacted] PASoF ¶236. "Immediate genericization" would

mean "No Financial Upside" because 13 prior settling Namenda generics had provisions in their agreements that provided for immediate and simultaneous market entry if Mylan won the patent dispute, lowering to nil Mylan's potential generic Namenda profits. PASoF ¶237.

The last slide, entitled "Reasons to Settle" drove this point home. Forest explained that its [redacted] PASoF ¶238. In other words, Forest's reverse payment to Mylan was "a sum even larger than what [Mylan] would gain in profits if it won the paragraph IV litigation and entered the market." *Actavis*, 133 S. Ct. at 2235.

5. The Lexapro Amendment and Mylan Patent Settlement Were Part of a Single Transaction

The [redacted] documents and the [redacted] explicitly present the Lexapro Amendment and Namenda patent settlement as a package. PASoF ¶240. Forest's in-house and outside counsel repeatedly referred to the Lexapro Amendment as a [redacted] to the Namenda patent dispute. PASoF ¶243. [redacted] PASoF ¶242. Forest's patent counsel confirmed that the Lexapro Amendment was a component of the Namenda patent settlement. PASoF ¶244. And Forest submitted to the Federal Trade Commission and the Department of Justice, a copy of the Lexapro Amendment, pursuant to Section 1112(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which requires the submission of agreements that are "contingent upon, provide a contingent condition for, or are otherwise related to" a Hatch-Waxman patent settlement agreement.[2] PASoF ¶245.

[2] Forest says the FTC, "brought no enforcement action." Def. Br. at 6. FTC states, "Any

6. Forest and Mylan Would Have Entered into the Lexapro Amendment, Even Without Its Reverse Payment Terms

Even without the payments proposed in the Mylan Deal Concept docments, [redacted] PASoF ¶¶250-51.

Plaintiffs' manufacturing expert, James Bruno, opines that [redacted]. PASoF ¶253.

7. Forest's Claimed Medicaid Rebate Savings Were Illusory and Artificially Inflated

Forest claims it projected that the Lexapro Amendment would lower its Medicaid rebate liability by [redacted], which should be viewed to offset the reverse payment. DSoF ¶¶215-235, 265. But Medicaid rebates are an obligation owed to the government, not Mylan, so they should not be viewed as a concession by Mylan akin to forgiveness of a debt or other obligation. PASoF ¶¶255-56. Instead, the Medicaid savings result from Forest charging a higher price to Medicaid for *brand* Lexapro, a product not even subject to the Original Lexapro Agreement or the Lexapro Amendment. PASoF ¶257.

It is undisputed that Forest was not required to make any reverse payment to Mylan to reap

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suggestions by drug companies to courts . . . that FTC inaction indicates the agreement presents no antitrust problem **would be inaccurate and improper.**" https://www.ftc.gov/system/files/attachments/competition-policy-guidance/050210pharmrulesfaqsection.pdf, last accessed Dec. 10, 2017.

Medicaid rebate savings. [redacted]. PASoF ¶¶258-61.

Moreover, Forest ginned up its Medicaid rebate savings forecasts with numbers that were inflated from about [redacted] to roughly match the [redacted] it agreed to pay Mylan the day before. PASoF ¶267. Specifically James Finchen, Forest's Medicaid analyst, circulated the second-to-last Medicaid rebate savings forecast on March 15, 2010, the same day the parties reached an agreement in principle on the Lexapro Amendment. PASoF ¶¶246-49, 265. The next day, Mr. Finchen adjusted several assumptions, including by applying an incorrect royalty rate, to generate a final analysis with savings equivalent to the reverse payment, and recirculated it in the same email chain. *Id.* Mr. Finchen made these adjustments after blindly applying incorrect inputs by members of primary negotiator David Solomon's team. Mr. Finchen admitted at deposition that correcting the royalty rates led to lesser rebate savings. PASoF ¶¶262-63. In other words, Forest did not finalize its rebate savings forecasts until *after* it agreed to pay Mylan [redacted].

8. There Is No Contemporaneous Evidence That Forest Thought Mylan Would Terminate the Original Lexapro Agreement After One Year

Forest claims that the Lexapro Amendment bound Mylan to a second year of AG Lexapro royalties it would not have had to pay if it terminated the Original Lexapro Deal after one year. DSoF ¶¶245-249. Forest recognizes that Mylan would have to pay a second-year royalty only if Product Profit was positive. *Id.* Forest also recognizes that, for those additional royalties to be attributable to the Lexapro Amendment, [redacted]. Forest and Mylan knew that there were *twelve* competitors waiting to launch generic Lexapro once Teva's 180-day exclusivity expired. PASoF ¶274. Faced with so many additional competitors, Mylan

[redacted]. PASoF ¶¶270-83.

First, [redacted] that Forest believed it would. All of Forest's AG Lexapro sales forecasts contain a list of assumptions, none of which is a one-year Mylan termination (instead they project market share and pricing from various points "onward"). PASoF ¶283. Moreover, Mylan did not have FDA approval to sell its ANDA version of Lexapro until 2015. PASoF ¶287. Even if Mylan received such approval, it could not have entered the market under its own generic Lexapro ANDA until six months later than if it sold Forest's AG, because as everyone knew, Teva was the first filer and held the 180-day exclusivity. PASoF ¶288. Selling Forest's AG Lexapro on "day 1" (actually, two weeks before "day 1") conferred on Mylan a first-mover advantage that was not achievable by selling its own non-authorized generic. *Id.* If Mylan changed from selling Forest's AG to its own ANDA generic, Mylan risked losing that first-mover advantage. *Id.*

[redacted]. PASoF ¶¶ 218 (g); 221(h).

Second, Forest had no reasonable basis to assume that a product with 12 competitors would be profitable and generate royalties in a second year. PASoF ¶275 (Bruno Reply ¶24 ("Based on my decades of experience in the pharmaceutical industry…there is no basis to assume that a drug

product with more than 10 competitors would continue to be profitable 12 months after generic entry"). Yet, Forest has produced (and its expert Mr. Green has relied upon) forecasts showing large royalties in a second year. These forecasts are not just implausible or mere innocent mistakes; rather, a jury could find they were purposely contrived attempts to create "offsets" to cover up the reverse payments. *Id*. (Berndt Reply ¶59 ("the forecasted benefits to Forest were so grossly unreasonable and unreliable, and seriously biased. I can only conclude that Forest's forecasts were not designed to provide Forest's executives with a rational expectation of how Forest would profit under the Forest-Mylan agreement as amended.")).

Even Forest's primary negotiator, Mr. Solomon, initially rejected Forest's implausible assumptions for Mylan's second-year AG Lexapro share, writing on January 13, 2010, that:

> AFTER 6 MONTHS MANY OTHER GENERICS WILL ENTER – SO I WOULD EXPECT MYLAN'S SHARE TO DECLINE TO A MUCH LOWER LEVEL – PROBABLY DECLINING TO SOMETHING LIKE 10-20%

PASoF ¶276. Forest's expert Mr. Green disregarded Mr. Solomon's statement. PASoF ¶277.

The dates of the forecasts also show that they were pretextual and/or created to hide Forest's reverse payment. Of the roughly 43 forecasts or analyses that Forest cites regarding the Lexapro Amendment (DSoF ¶¶215, 236), 34 were generated between January 7 and January 20, 2010 (the day before the January settlement meeting between Forest and Mylan) and only projected profits from the first year of sales. PASoF ¶284. The remaining 7 that purported to show expected profits in the second year (and beyond) were generated between March 15 and March 16, 2010 (*id*.), the day of and the day after the parties agreed in principle to the Namenda patent settlement and the Lexapro Amendment (*i.e.*, *after* negotiations on the Lexapro Amendment had concluded). PASoF ¶¶246-49. A jury could conclude that these 7 "second year" forecasts – created *after* agreement on the Lexapro Amendment was reached – were not created as part of Forest's evaluation of settlement terms but for a nefarious purpose.

[redacted]. PASoF ¶¶278-79. Unlike Plaintiffs' expert, Forest's Mr. Green [redacted] PASoF ¶280; PASoF ¶275.

In fact, akin to Mylan's objectively reasonable prediction, and as Forest's expert Mr. Green was forced to recognize, [redacted] PASoF ¶281. Mylan thus predictably owed no royalty to Forest in the second year of AG Lexapro sales, [redacted] Forest's March 15-17, 2010 analyses and forecasts, purporting to show otherwise, were simply post-hoc rationalizations. PASoF ¶¶275, 286.

B. But-For the Reverse Payment Agreement, Mylan and Other Generic Competitors Would Have Entered the Market Earlier

Plaintiffs' experts have concluded, based on the evidence, that absent the reverse payment, Mylan would have launched generic Namenda IR far earlier. Prof. Elhauge concludes that Mylan and Forest would have agreed to a no-payment settlement "with an entry date of November 2, 2012, about 26.3 months prior to the settlement entry date of January 11, 2015 agreed upon with the reverse-payment settlement." PRSoF ¶332. At least four additional generic Namenda IR manufacturers would have then entered the market pursuant to the contingent launch clauses in their Namenda patent settlement agreements. None of the five ([redacted]) had any supply, equipment, or manufacturing issues that would have prevented a generic Namenda IR from being marketed any time after June 2012. PASoF § D.

C. Forest's Hard-Switch Product Hop

Forest launched Namenda XR in June 2013. PASoF ¶296; PRSoF ¶358. Forest had long modeled both a "withdrawal" or "hard switch" scenario, and a "conventional" or "soft switch" scenario. PASoF ¶302; PRSoF ¶¶312, 314. Forest modeled the expected conversion rate from a soft switch for more than a year before launch. PASoF ¶314. Forest's forecasts [redacted]. PASoF ¶¶302, 305-06, 318. Forest [redacted]. PASoF ¶296. Indeed, Forest employees learned from managed care representatives that it was critical to launch XR at least eighteen months before entry of the IR generic. PASoF ¶296; PRSoF ¶371. Thus, Forest's analysts were able to rely upon a very thorough analysis of the market in preparing their forecasts. As this Court has already found, Forest's analysts routinely projected that Forest would attain approximately 30% conversion to Namenda XR by employing soft switch strategies. Litvin Decl. Ex. 355, Estoppel Op. at 24).

Forest launched Namenda XR with a massive promotional blitz and an aggressive campaign to secure favorable formulary coverage. PASoF ¶308; PRSoF ¶363. But, cognizant of the fact that there was no significant clinical advantage to Namenda XR over Namenda IR (PASoF ¶¶304, 309-10), Forest closely monitored its progress towards its target conversion rate. PASoF ¶¶308, 313. Forest executives discussed the hard switch option during quarterly investor calls (PASoF ¶¶311, 343-44), and Forest determined internally that [redacted]. PASoF ¶312. By October 18, 2013, Forest determined that the soft switch was not going as well as hoped and decided to implement the hard

switch. PASoF ¶¶320-21, 325, 338.

Forest telegraphed the announcement before it was made, using it to convince its most crucial pharmacy benefit manager, Optum, which controlled 21% of Medicare Part D (Namenda's most significant market), to accept its rebate agreement and give Namenda XR favorable formulary status. PASoF ¶¶340-41; PRSoF ¶373. Forest knew that by broadcasting the withdrawal announcement, it would "accelerate" conversion. *Id*. Moreover, Forest understood that "over-communication" of the withdrawal announcement would change physician prescribing habits from IR to XR, which would not be reversed, because "old habits die hard." PASoF ¶347-49, 350; PRSoF ¶¶359, 398, 412, 472.

On February 14, 2014, Forest formally announced that it would withdraw Namenda IR by August 15, 2014. PASoF ¶342. Forest's press release was followed by an intense promotional campaign to induce physicians to immediately switch their patients from Namenda IR to XR. PASoF ¶¶350-69; PRSoF ¶484. Forest sent out millions of communications, both directly and via third parties (including over 2.6 million communications from just one third-party vendor). PRSoF ¶425. Forest also unleashed its army of detail representatives to drill into physicians, caregivers, health care entities, and patients that they should switch to Namenda XR now to avoid disruption upon IR's withdrawal. PASoF ¶¶361-69; PRSoF ¶484. The message was clear: physicians should immediately stop prescribing Namenda IR and prescribe Namenda XR. PASoF ¶368. Forest reinforced this message over and over with written, electronic, and interpersonal communications into the summer of 2014. PASoF ¶368. Even when Forest faced a supply disruption for Namenda XR, it told the market that it would still discontinue Namenda IR in the Fall. PASoF ¶368. Forest also stopped making Namenda IR so that (as Forest told the Second Circuit) "physicians would transition patients to Namenda XR." PRSoF ¶397.

After a hearing, Judge Sweet enjoined Forest from actually discontinuing sales of Namenda IR until after generics entered. PASoF ¶371. Forest was required to inform the market of the injunction and the "continued availability of Namenda IR in the same or substantially similar manner in which they informed [it] of Defendants' plan to discontinue Namenda IR in February 2014." *Id.*

Forest responded, however, by issuing press releases announcing it was appealing the injunction and was "optimistic" the injunction would be overturned; and then by informing the market it was appealing, *i.e.*, challenging the injunction and asking a higher court to overturn it (as Forest's own expert concedes). PRSoF ¶¶397-98, 430, 484. Forest understood that the key to conversion was to change physician prescribing habits (PRSoF ¶¶397, 412, 472, 487), and Forest's emphasis on its appeal continued to sow fear, uncertainty, and doubt about whether Namenda IR would be available. Forest hardly rectified its prior six-month campaign of telling physicians, caregivers, and health care providers about Forest's intent to discontinue Namenda IR. Indeed, Forest did not drop its public legal challenge to the injunction until November 2015, after generic IR had belatedly entered. PRSoF ¶397.

As a result of the hard switch, the communications amplifying it, and Forest's inadequate corrective measures, Forest wrongfully inflated its conversion rate well over the 30% soft-switch rate, as this Court found in its estoppel opinion. PRSoF ¶488 (quoting Estoppel Op. at 24).

III. ARGUMENT

A. The Court Should Deny Summary Judgment on the Reverse-Payment Claim

1. Pertinent Law

The Court previously set forth the three-part rule of reason burden shifting framework:

> First, the plaintiff bears the initial burden of showing that the defendant's conduct had an actual adverse effect on competition as a whole in the relevant market. If plaintiff satisfies this burden, the burden then shifts to defendant to offer evidence

> that its conduct had pro-competitive effects. If defendant is able to offer such proof, the burden shifts back to plaintiff, who must prove that any legitimate competitive effects could have been achieved through less restrictive alternatives.

Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC, No. 15-cv-6549 (CM), 2016 WL 4992690, *13 (S.D.N.Y. Sep. 13, 2016) ("MTD Op.") (citation omitted). Under *Actavis* (133 S. Ct. at 2237), plaintiffs bear the burden on the first prong, by showing a large reverse payment. *See King Drug Co. of Florence, Inc. v. SmithKline Beecham Corp.*, 791 F.3d 388, 411, 412 (3d Cir. 2015) ("*Lamictal*") ("First, to prove anticompetitive effects, the plaintiff must prove payment for delay[.] * * * Second, the burden then shifts to the defendant to show that legitimate justifications are present, thereby explaining the presence of the challenged term[.] * * * Finally, the plaintiff will have the opportunity to rebut the defendant's explanation."); *King Drug Co. of Florence v. Cephalon, Inc.*, 88 F. Supp. 3d 402, 422 (E.D. Pa. 2015) (under *Actavis*, "a plaintiff … must demonstrate anticompetitive effects, including a large reverse payment, under the first step of the rule of reason. The defendant then bears the burden of explaining or justifying the payment as procompetitive. If the plaintiff presents evidence to raise a factual dispute as to defendant's proffered justifications, the fact-finder will weigh all relevant information and determine whether the settlement was, on balance, unreasonable").

a. Large Reverse Payment and Anticompetitive Effect

i. Large Reverse Payment

A large reverse payment under *Actavis* is one that exceeds the payor's (here, Forest's) litigation costs avoided by the settlement. *See Actavis*, 133 S. Ct. at 2237 (payment is to be measured "in relation to the *payor's* anticipated future litigation costs") (emphasis added); MTD Op., 2017 WL 4992690, at *14-15 (The Supreme Court "instructed courts [] to compare a payment to the payor's future litigation costs as a measure of scale to determine if it was 'large'") (citing *Actavis*, 133 S. Ct. at 2237).

Contrary to Defendants' argument on pages 36-37 of their brief, "large" is *not* defined with reference to the brand's profits. *Actavis* underscored – twice – that it is impermissible to judge the payment size based on the revenues the brand company could earn for the patented product. First, the Supreme Court said defendants could be liable even if the payment was small enough in relation to branded drug revenues to be easily recouped by the brand company:

> Solvay's patent, if valid and infringed, might have permitted it to charge drug prices **sufficient to recoup the reverse settlement payments it agreed to make** to its potential generic competitors. And we are willing to take this fact as evidence that the agreement's anticompetitive effects fall within the scope of the exclusionary potential of the patent. **But we do not agree that that fact, or characterization, can immunize the agreement from antitrust attack**.

133 S. Ct. at 2230 (emphasis added; citation omitted). Second, the Supreme Court was clear that the "earning potential" of the drug at issue (*i.e.*, the brand drug's monopoly profit stream) is *not* a relevant comparator. *Id.* at 2231 ("earning potential" of patent is not what courts should measure the restriction against).[3] This makes sense: because a brand's (monopoly) profits far exceed a generic's (competitive) profits, a brand need not pay a "large" portion of its patent-protected profits to induce delay. *See King Drug Co. of Florence*, 88 F. Supp. 3d at 417 (*Actavis* "seems to contradict the argument that the brand manufacturer's expected monopoly profits constitutes the appropriate benchmark" for a large reverse payment (citation omitted)).

ii. Anticompetitive Effect

The anticompetitive effect from a reverse-payment agreement is the "maint[enance of] supracompetitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market[.]" *Actavis*, 133 S. Ct. at 2236. If a plaintiff adduces proof of higher prices due to the reverse payment, summary judgment should be denied. *See Laumann*

[3] In addition, the payments made by the brand to the generics in *Actavis* came nowhere near the brand revenues during the period of delay.

v. NHL, 56 F. Supp. 3d 280, 297-98 (S.D.N.Y. 2014) ("Plaintiffs have carried their initial burden of showing an actual impact on competition. The [defendants] have entered an express agreement to limit competition. * * * There is also evidence of a negative impact on the output, price, and perhaps even quality. . ."); *Fleischman v. Albany Med. Ctr.*, 728 F. Supp. 2d 130, 164 (N.D.N.Y. 2010) (summary judgment denied in rule of reason case because "[p]laintiffs have provided sufficient evidence of anticompetitive effect" and "harm to competition" from challenged conspiracy); *Rome Ambulatory Surgical Ctr. v. Rome Mem. Hosp.*, 349 F. Supp. 2d 389, 409 (N.D.N.Y 2004) ("Plaintiff may demonstrate actual adverse effects on the market by a showing reduced output, increased prices, decreased quality, or the imposition of entry barriers."); *Clorox Co. v. Sterling Winthrop*, 836 F. Supp. 983, 989 (E.D.N.Y. 1993) ("to survive summary judgment [in a rule of reason case], a plaintiff must raise a genuine issue of fact concerning the anticompetitive effect of the challenged restraint").

b. Procompetitive Explanations or Justifications

i. Defendants Bear the Burdens of Production and Proof

Once Plaintiffs have established that Forest's conduct had an actual adverse effect on competition, "the burden then shifts to [Forest] to offer evidence that its conduct had pro-competitive effects." *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 104 (2d Cir. 2010), *rev'd on other grounds, Actavis*, 133 S Ct. 2223. *See also Virgin Atl. Airways v. British Airways PLC*, 257 F.3d 256, 264 (2d Cir. 2001) (once an adverse effect on competition is shown, "the burden shifts to [defendant] to establish the procompetitive value of its[] agreements"); *Rome Ambulatory Surgical Ctr.*, 349 F. Supp. 2d at 407 (same). Thus, a procompetitive justification is an affirmative defense for which the defendant bears the burdens of production and persuasion. *NCAA v. Bd. of Regents*, 468 U.S. 85, 113 (1984) ("the Rule of Reason … place[s] upon [defendant] a heavy burden of establishing an affirmative defense which competitively justifies

this apparent deviation from the operations of a free market.")

Under *Actavis*, there are two possible justifications: a reverse payment is less than the payor's saved litigation costs or represents "fair value for services" performed by the generic manufacturer. *Actavis*, referring specifically to the defense that "[t]hat [the] payment may reflect compensation for other services that the generic has promised to perform," clearly put the burden on *defendants* to show the brand's payment was "fair value for services." 133 S. Ct. at 2236 ("An antitrust *defendant* may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason.") (emphasis added); *id* at 2237 ("one who makes such a payment may be unable to explain and to justify it"). All courts recognize this. In *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256-57 (3d Cir. 2017) (emphasis in original), the Third Circuit held that "[t]he Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants . . . An antitrust defendant* may show in the antitrust proceeding that legitimate justifications are present." *See also King Drug Co. of Florence*, 88 F. Supp. 3d at 419-20 ("Defendants, not Plaintiffs, bear the burden of explaining the payments …[E]vidence that these payments exceed fair value for goods and services …are not a necessary element of plaintiffs' claims."); *In re Opana ER Antitrust Litig.*, 162 F. Supp. 3d 704, 718 (N.D. Ill. 2016) (with respect to whether a payment is "justified" because it reflects "fair value for services," "[t]he burden is on the defendant to 'show in the antitrust proceeding that legitimate justifications are present . . .'") (quoting *Actavis*, 133 S. Ct. at 2236); *In re Nexium (Esomeprazole) Antitrust Litig.*, 42 F. Supp. 3d 231, 263-64 (D. Mass. 2014) ("Nowhere in *Actavis* does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny. Neither does the opinion place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something

other than fair market value."). Leading commentators agree that the burden of justifying a reverse payment remains with the defendants. *See* Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating* Actavis, 28 Antitrust 16, 18 (2013) ("The defendants have the burden of production [and of] proving that the payment was for valuable services, rather than delay.").

ii. Fact Questions About the Validity of Justifications Preclude Summary Adjudication

A plaintiff can defeat summary judgment by showing that a defendant's proffered justifications are pretextual,[4] or questionable for other reasons. *See Eastman Kodak Co. v. Image Tech. Servs.*, 504 U.S. 451, 483 (1992) ("Factual questions exist, however, about the validity and sufficiency of each claimed [procompetitive] justification, making summary judgment inappropriate."); *In re K-Dur Antitrust Litig.*, No. 01-1652, 2016 WL 755623, at *12 (D.N.J. Feb. 25, 2016) (summary judgment denied due to dispute over whether license from generic back to brand explained reverse payment or was pretextual); *Gregory v. Fort Bridger Rendezvous Ass'n*, 448 F.3d 1195, 1205 (10th Cir. 2006) ("Whether the conspirators' justification for its conduct is pretextual . . . is properly considered under the rule of reason analysis."); *Klickads, Inc. v. Real Estate Bd. of N.Y.*, No. 04-cv-08042, 2007 WL 2254721, *8 (S.D.N.Y. Aug. 6, 2007) (summary judgment "inappropriate" "[b]ecause substantial questions of fact exist with respect to… procompetitive justifications"); *Fox v. Good Samaritan Hosp.*, 2007 WL 2938175, *10 (N.D. Cal. Oct. 9, 2007) (denying summary judgment where "there is evidence. . . from which one could infer that . . . the reason given for the implementation of the rule was pretextual."); *Rome Ambulatory*

[4] To be cognizable, Forest's asserted justifications must not be pretextual. *See New York v. Actavis PLC*, 787 F.3d 638, 652 (2d Cir. 2015) ("the monopolist may proffer 'nonpretextual' procompetitive justifications for its conduct. The plaintiff may then either rebut those justifications or demonstrate that the anticompetitive harm outweighs the procompetitive benefit.") (citation omitted).

Surgical Ctr., 349 F. Supp. 2d at 411 (plaintiffs exposed "[a] logical disconnect in defendants' argument" which "is sufficient to raise a question of fact as to its justification"); *id.* ("[m]aintaining patient volume is certainly good for *the Hospital*, but defendants have not conclusively demonstrated that it in any way benefitted *competition*.") (emphasis added); *Laumann*, 56 F. Supp. 3d at 302 (summary judgment denied where "[m]ost of defendants' claimed pro-competitive effects are disputable, and the overall effect on the economy is even less conclusive.").

iii. Less Restrictive Means of Achieving a Procompetitive Benefit

For an asserted procompetitive justification to reach the jury, the challenged restriction on competition must be the least restrictive means of achieving the procompetitive goal. *See NASL v. NFL*, 670 F.2d 1249, 1261 (2d Cir. 1982) (defendant failed to prove the "market necessity" of its ban on team owners also owning soccer teams, and "[m]oreover, the NFL was required to come forward with proof that any legitimate purpose could not be achieved through less restrictive means. This it has failed to do."). A jury may not consider a defendant's justification if the challenged restraint – here, the reverse payment to Mylan and associated delay – was not the least restrictive means to achieve the claimed procompetitive benefit. *See* Ch. 1, Instruction 3-C, ABA Model Jury Instructions in Civil Antitrust Cases (2016) at Notes ("If plaintiff proves that the same benefits could have been readily achieved by other, reasonably available alternative means that create substantially less harm to competition, then they cannot be used to justify the restraint.").

c. Balancing

The third step is balancing the anticompetitive harm against any proven, nonpretextual procompetitive justifications. It is the jury that has the final say on whether, after weighing the totality of circumstances, a challenged agreement violates the rule of reason. "The principal question in a rule of reason case is often whether the anticompetitive effects of a restraint are

outweighed by some procompetitive justification." *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238 (2d Cir. 2003). "Such an issue of material fact should not be resolved at the summary judgment stage because to do so requires weighing the evidence, which is a matter left for a jury." *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 501 (2d Cir. 2004) (reversing summary judgment in antitrust case because "Plaintiffs have satisfied their burden of producing evidence that the effects of Barr's advantage were substantial and that competition overall was impaired."); *Lamictal*, 791 F.3d at 411 ("If genuine issues of material fact remain after discovery, the rule-of-reason analysis is for the finder of fact, not the court as a matter of law.").

d. Linkage Between Agreements

In addition to the direct linkage supplied by the "Mylan Deal Concept" documents the Forest-Mylan settlement presentation, [redacted], the Forest-Actavis merger agreement, and Forest's FTC filings (*see* Parts II.A.3 & 5, *supra*), a reasonable jury can find that agreements executed simultaneously among the same parties, like the Namenda patent settlement and the Lexapro Amendment, comprise a single transaction. *See TVT Records v. Island Def Jam Music Grp.*, 412 F.3d 82, 89 (2d Cir. 2005) (it is "typically a question of fact for the jury" whether writings are part of a single transaction or not); 11 Williston on Contracts § 30:26 (4th ed.) ("whether separate agreements are actually part of a single transaction is a question of fact, dependent on the intent of the parties"). *See also Opana*, 162 F. Supp. 3d at 717 ("it is improper to view the components of the Endo-Impax Settlement in isolation.") (citation omitted); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 752 (E.D. Pa. 2014) ("[T]he Licensing Agreement must be read in conjunction with the Co-Promotion and Manufacturing Agreements executed that same day.").

2. Issues of Fact Remain on Plaintiffs' Reverse Payment Claim

a. Forest Made a $[redacted] Reverse Payment to Mylan

There is no dispute that the Lexapro Amendment conferred $[redacted] to Mylan, and [redacted] PRSoF ¶¶243, 255, 260, 274; PASoF ¶¶221(b)-(d). *See TVT Records*, 412 F.3d at 89. Plaintiffs' economic expert, Professor Elhauge, testified that the $[redacted] million Forest conferred to Mylan under the Lexapro Amendment made no economic sense *unless* it was linked with the Namenda patent settlement agreement. PASoF ¶244. David Solomon (for Forest) and [redacted] negotiated both deals contemporaneously. PASoF ¶234. [redacted]. PASoF ¶290. Forest's economic expert, Dr. Fowdur, cited this testimony in her report, conceding that linkage. *Id*. [redacted]. *Id*. No jury would be required to believe Forest's story that the Lexapro Amendment and Namenda patent settlement were unrelated. The other evidence demonstrating the linkage is overwhelming. PASoF ¶¶240-45, *supra* at Parts III.A.3 & 5.

Nor can there be any dispute that the reverse payment was large: it was [redacted] times Forest's saved litigation costs of $[redacted]. PRSoF ¶280. As the cases cited in Part III.A.1.a.i, *supra*, show, this satisfies Plaintiffs' obligation to show a large payment. *See* MTD Op., 2016 WL 4992690, at *12-13; *In re Actos End Payor Antitrust Litig.*, No. 13-cv-9244, 2015 WL 5610752, *19 (S.D.N.Y. Sept. 22, 2015), *aff'd in part and rev'd in part*, 848 F.3d 89, 97 (2d Cir. 2017).

Moreover, as Forest emphasized [redacted] (*see* Part

II.A.4, *supra*), [redacted]" PASoF ¶¶235-38. That admission dooms Forest's motion, as a reverse payment larger than what the generic manufacturer would earn from competing is large as a matter of law. *Actavis*, 133 S. Ct. at 2235 ("Indeed, there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market."); *Lidoderm*, 74 F. Supp. 3d at 1071 ("a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market" is "at one extreme"); *King Drug Co. of Florence*, 88 F. Supp. 3d at 418 ("A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim. * * * As *Actavis* explains, the relevant inquiry is what would induce the generic to stay off of the market.").

b. Forest's Explanations for the Reverse Payment Are Disputed

Forest argues that there are explanations for its $[redacted] reverse payment other than a payment for delay. Forest's primary expert, Mr. Green, could not say, however, what Forest's $[redacted] upfront payment to Mylan was for (PASoF ¶290). Yet, Forest now relies on Mr. Green, an accountant, to argue that Mylan supposedly promised to give money and services back to Forest that are valued at or around [redacted]. Though each of Forest's explanations is contrived (and obviously disputed), Forest argues that a jury would be *required* to accept them. Not so. Nor can Forest shift the burden of explaining a reverse payment to Plaintiffs. As shown in Part IIIA.1.b above, *Forest* bears the burdens of production and proof on its explanations and "fair value" defenses, and so summary judgment on this claim is doubly inappropriate. Even in other contexts,

fair value for services is an issue of fact.[5] A jury will have to evaluate Forest's explanations.

i. Forest's "Second Year of Authorized Generic Lexapro" Explanation is Pretextual and Disputed

Forest's first justification for its $[redacted] payment to Mylan is that it was paid to convince [redacted] Mylan to continue selling AG Lexapro for a second year instead of terminating after one year, cementing a second year of royalties for Forest. But there is no credible evidence to support this excuse, and no jury would be required to believe it.

Forest claims, based on post-hoc 30(b)(6) deposition testimony by David Solomon in this case, only that *it* was worried that Mylan would terminate after one year. DSoF ¶246 [redacted]"). [redacted] The contemporaneous evidence shows the opposite. [redacted] (*see* Part II.A.3, 5 & 6, *supra*), [redacted]. PASoF ¶250. [redacted]

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[5] *See Eisenberg v. CIR*, 155 F.3d 50, 53 n.9 (2d Cir. 1998) ("A determination of fair market value, being a question of fact, will depend upon the circumstances in each case.") (quoting Revenue Ruling 59-60, P3.01); *ASCAP v. Showtime/Movie Channel*, 912 F.2d 563, 569 (2d Cir. 1990) ("Fair market value is a factual matter[.]"); *Ocean Walk, Ltd. v. Certain Underwriters at Lloyd's*, No. 03-cv-05271, 2006 WL 2689626, at *9 (E.D.N.Y. Sept. 19, 2006) ("Yet, it is a difficult task to establish valuation as a matter of law; rather, the determination of [fair market] value is normally one for the fact-finder.").

[redacted]

PASoF ¶270.

Plaintiffs have also demonstrated that it would have been economically irrational for Mylan to terminate after year one, because it would make less money. O'Shaughnessy Decl. Ex. 122, Elhauge Rebuttal Rpt. ¶18. In addition, Mylan did not have final FDA approval to sell its own ANDA generic Lexapro until 2015, and Mylan did not launch even then. PASoF ¶287. And even with FDA approval for its ANDA, [redacted], because Teva was the first filer and held the 180-day exclusivity. PASoF ¶288. [redacted] If Mylan changed from Forest's AG to Mylan's own generic, Mylan risked losing that first-mover advantage. *Id.* Further, Plaintiffs have shown a "second year" promise by Mylan was illusory (and so worth nothing extra to Forest), [redacted]. PASoF ¶¶218(g), 221(h).

In addition, with up to 14 generic drug companies lined up to compete in the generic Lexapro market six months after Teva's launch, no reasonable drug company could have expected Mylan's AG sales to maintain the share and pricing needed to generate royalties for Forest in year two. *See* Part II.A.8, *supra*. Indeed, just six months after Mylan started selling AG Lexapro in February 2012, multiple generics entered, Mylan's price and share dropped, and Mylan's royalty obligation to Forest [redacted]. PASoF ¶281. [redacted] PASoF ¶279. [redacted] PASoF ¶280. [redacted]

[redacted]

PASoF ¶276 (capitalization in original). Mr. Green simply disregarded Mr. Solomon's words in favor of other documents. PASoF ¶277. Forest's other expert, Dr. Fowdur, relies entirely on Mr. Green's analysis. O'Shaughnessy Decl. Ex. 54, Fowdur Report ¶52. Plaintiffs' experts have shown that these forecasts are utterly implausible. PASoF ¶275 (Plaintiffs' expert Mr. Bruno: "Based upon my decades experience in the pharmaceutical industry, including in profit sharing contracts, there is no basis to assume that a drug product with more than 10 competitors would continue to be profitable 12 months after generic entry); *id.* (Plaintiffs' expert Dr. Berndt: "The assumptions reflected in the Forest documents that Mr. Green uncritically relied upon were completely at odds with the contemporaneous literature that would underlie any reasonable analysis of expected market share, generic pricing, and anticipated profit from the AG.").

The so-called "second year" forecasts which Forest now relies on were generated [redacted] (PASoF ¶¶246-49), so they could not have served as a basis to evaluate a proposed second year. PASoF ¶¶284-87. A reasonable jury could find that the Forest forecasts were a fig-leaf designed to hide the $[redacted] reverse payment.

ii. Forest's "Medicaid Liability Reduction" Explanation is Disputed and Pretextual

Forest's second explanation for the $[redacted] reverse payment is that it compensated Mylan for accepting manufacturing responsibility for AG Lexapro, which avoided $[redacted] in Medicaid rebate liability on Forest's sales of *branded* Lexapro, which was not the subject of

either the Lexapro Amendment or the Original Lexapro Agreement. *See* PASoF ¶¶254-69. There are several serious problems with this explanation.

[redacted]. *See* PASoF ¶253.

Second, the $[redacted] of avoided rebate liability that Forest touts came from the U.S. Treasury, *not* Mylan. *See* PASoF ¶¶255-56. The avoided rebate liability is merely an incidental benefit to Forest that does not affect the value Mylan received. To say that the $[redacted] in avoided rebate liability offsets the $[redacted] reverse payment is a *non sequitur*, because of the disconnect between payor and payee, and between the reason for the payment and the reason for the offset. It is also legally irrelevant. *See* Part III.A.2.b.iii, *infra*.

[redacted]. As explained in Part III.A.1.b.iii. above, for a procompetitive justification to be considered, the reverse payment must be the least restrictive means of achieving the asserted procompetitive benefit. *See NASL*, 670 F.2d at 1261. [redacted], when it was in Mylan's economic interest to do so for no payment.

Fourth, there is substantial evidence that the claimed Medicaid reduction was inflated and is thus also a pretextual attempt to paper over the $ million reverse payment. – DSoF ¶¶202-03), . PASoF ¶¶225-38, 284, 286. And Forest employees manipulated the rebate liability analyses to inflate the forecasted rebate savings to just about equal the reverse payment to Mylan. . PASoF ¶¶265-67; Part II.A.7, *supra*. . PASoF ¶¶265-67. PASoF ¶263. PASoF ¶268. From this sequence of events, a reasonable jury could infer an attempt on Forest's part to manipulate its rebate avoidance and create analyses to disguise the reverse payment to

Mylan, revealing Forest's entire rebate liability argument to be pretextual.

Finally, even if Forest could convince a jury to offset [redacted], an unexplained reverse payment remains. PASoF ¶269. This points out a substantial flaw in Forest's sole fair valuation expert, Mr. Green's, opinion: even if the jury were to accept his creative Medicaid rebate accounting, Forest still made an actionable reverse payment to Mylan. PASoF ¶ 288, fn 3. If the jury rejects Mr. Green's first explanation for the reverse payment (the "second year" argument, discussed above) then it will be required to find that Forest – which under controlling law bears the burdens of production and persuasion in explaining and justifying its payments to Mylan – made a large reverse payment to Mylan. PRSoF ¶ 266; O'Shaughnessy Decl. Ex. 69 ¶ 75.

iii. The Diminished Medicaid Rebate Liability Does Not Shrink the Reverse Payment

Mr. Green's creative Medicaid accounting is irrelevant in any event, because as a matter of law Forest should not be able to offset its payment by any amount with a tangential benefit it received from a third party – here, the government, via a reduced Medicaid rebate for brand Lexapro, a product not subject to either the Namenda settlement or the Lexapro Amendment. *See* Def. Br. at 17, 25-28. Forest's argument is illogical under *Actavis*, the thrust of which was to ascertain whether the payment induced *the generic* to quit the patent fight. *Actavis*, 133 S. Ct. at 2235 (where a payment is larger than what the generic would receive by competing, "[t]he payment may instead provide strong evidence that the patentee seeks **to induce the generic** challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market.") (citations omitted) (emphasis added). This is such a case. *See* PASoF ¶¶238, 241 [redacted]

In re Loestrin 24 Fe Antitrust Litig., No. MDL No. 13-2472-S-PAS, 2017 WL 3600938, at *17 (D.R.I. Aug. 8, 2017) emphasized that "[t]he [Supreme] Court's use of the word 'induce' ***suggests that the value to the alleged infringer is paramount***, whereas the emphasis on the 'share of its monopoly profits' supports the notion that the brand must be alleged to have sacrificed some amount of its anticipated profits in order to maintain its monopoly.") (emphasis added). That Forest could avoid a Medicaid liability does not negate that it paid Mylan from its monopoly profits. Only a return of value ***from Mylan*** could do so. And as Judge Underhill explained in *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (emphasis added), a reverse payment is unlawful if "viewed holistically, it effects a large and unexplained *net transfer of value from the patent-holder to the alleged patent-infringer*." Value external to the transfer logically does not inform whether there has been a net transfer of value *between* the settling parties. Specifically, the Medicaid rebate savings does not represent a transfer of value *from* Mylan back *to* Forest. Forest's Medicaid expert admitted that the rebates were not an obligation Forest would have otherwise owed Mylan. PASoF ¶¶255-56. Hence, they cannot net against what Mylan received. *Actavis* and its progeny confirm that a benefit untethered to a reverse payee's obligation does not factor into a fair value analysis. *See, e.g.*, *Loestrin*, 2017 WL 3600938, at *19 (defendants must show that the payment was for "fair value for services ***the generic manufacturer promised to perform***.") (emphasis added). [redacted].

Even if Forest may deduct from its reverse payment benefits it received that were unrelated to any services Mylan provided, Forest should not be entitled to net out the entire purported Medicaid benefit. First, doing so assumes that the entire benefit should be attributed to the [redacted] reverse payment. But as Prof. Elhauge explains, on a standalone basis, it would have been

beneficial to both parties to enter the Lexapro Amendment without a payment. PASoF ¶¶250-52. Second, Forest could have achieved the same Medicaid savings by contracting with a third party to manufacture AG Lexapro for Mylan. PASoF ¶¶258-61.

Forest cites *Lamictal*, 791 F.3d at 404-05, to suggest that the *Actavis* analysis turns on whether the brand gave up more value than it received. That reading is incorrect. In that case the Third Circuit merely explained that a promise from a brand to not launch an AG was equivalent to a transfer of cash, because cash and a promise not to launch an AG both *have value to the generic*. As the court explained in the paragraph following the quote Defendants cite:

> If the brand uses a no-AG agreement **to induce the generic** to abandon the patent fight, the chance of dissolving a questionable patent vanishes (and along with it, the prospects of a more competitive market). As with **a reverse payment** of cash, a brand agreeing not to produce an authorized generic **may thereby have "avoid[ed] the risk of patent invalidation or a finding of noninfringement."** *Id.* at 2236. In addition, when the parties' settlement includes a no-AG agreement, the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted.

Id. at 405 (emphasis added). The Third Circuit's analysis is clearly fixed on the size of the reverse payment from the generic's point of view.

iv. [redacted]

[redacted]

B. Causation Is Established, or There Remain Material Disputed Facts

Plaintiffs have asserted two alternative causation scenarios, each fully supported by the record: (1) but-for Forest's reverse payment, Forest and Mylan would have entered a no-payment settlement with an earlier entry date based on the bargaining strength of the parties; and (2) absent a settlement Mylan would have prevailed in the patent litigation and entered earlier than the agreed-to entry date.

1. Causation Is a Question for the Jury

The Supreme Court has held that "[t]he issues of proximate causation and superseding cause involve application of law to fact, **which is left to the factfinder**, subject to limited review." *Exxon Co., USA v. Sofec, Inc.*, 517 U.S. 830, 840-41 (1996) (emphasis added); *Armstrong v. U.S.*, 756 F.2d 1407, 1409 (9th Cir. 1985). Courts in this Circuit and elsewhere have held the same in

[6] Plaintiffs' expert valued the claims at [redacted] after trebling. PASoF ¶ 291.

the context of pharmaceutical antitrust cases. *La. Wholesale Drug Co. v. Sanofi-Aventis*, No. 07 CV 7343 (HB), 2008 WL 4580016, at *5 (S.D.N.Y. Oct. 14, 2008) ("at minimum this is a jury question"); *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) (causation is "best left to the jury") (citing *Callahan v. A.E.V., Inc.*, 182 F.3d 237, 257 (3d Cir. 1999)); *id.* at 628 ("Proximate cause and intervening cause are usually issues for the jury to decide.") (citation omitted); *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2013 WL 4042460, *9-10 (D.N.J. Aug. 8, 2013) (summary judgment inappropriate where cause of delay was disputed) (citing *Rivas v. City of Passaic*, 365 F.3d 181, 193 (3d Cir. 2004)); *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *23 (D.N.J. Sept. 5, 2013) (possibility of earlier generic entry a jury question), *rev'd on other grounds*, 868 F.3d 231; *Andrx Pharm., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799, 808-09 (D.C. Cir. 2001) (same); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 649–50 (E.D. Mich. 2000) (sufficient evidence to support inference of causation creates a jury question). *See also In re Currency Conversion Fee Antitrust Litig.*, 773 F. Supp. 2d 351, 373 (S.D.N.Y. 2011) (denying summary judgment because jury could find conduct caused injury to competition).

"In the antitrust context, plaintiffs enjoy a considerable amount of leeway in 'constructing a hypothetical world free of the defendant's exclusionary activities.'" *Univac Dental Co. v. Dentsply Int'l, Inc.*, No. 1:07–CV–0493, 2010 WL 1816745, *3 (M.D. Pa. Apr. 27, 2010). Courts therefore routinely deny defense motions based on causation grounds that seek to hold plaintiffs to an unrealistically high standard in proving a "but for" world free from the alleged antitrust violation. *See, e.g., In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, at *11 (D.N.J. 2009). *See also Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265 (1946) ("most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created . . . Any other rule would enable the wrongdoer

to profit by his wrongdoing at the expense of his victim.").

2. Argument

a. Forest and Mylan Would Have Entered into a Procompetitive Settlement Absent the Anticompetitive Reverse Payment

Forest argues that "showing that the alternative agreement *may* have happened simply does not satisfy the [Plaintiffs'] burden." Def. Br. at 41 (citing *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 167 (3d Cir. 2017)) (emphasis in original). But Plaintiffs do not contend that Mylan "may" have entered the Namenda market but-for Forest's reverse payment. Rather, Plaintiffs have sufficient evidence (not speculation) that Mylan *would* have entered earlier via either: (1) a settlement agreement *without* the payment that purchased delay; or (2) prevailing in the '703 patent litigation and entering the market thereafter.

i. Objective Evidence Establishes that Forest and Mylan Would Have Agreed to a No-Payment Settlement with an Earlier Entry Date

Antitrust cases employ a "comparison of [] prices [] as affected by the [antitrust violation], with what they would have been in its absence under freely competitive conditions." *Bigelow*, 327 U.S. at 264. In other words, the but-for world is "free of the restraints and conduct alleged to be anticompetitive." *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005). *See also Apotex, Inc. v. Cephalon, Inc.*, 321 F.R.D. 220, 236 (E.D. Pa. 2017) ("When recreating a but-for world to establish antitrust damages, a plaintiff must create a world 'characterized by the absence of the … challenged practices.'") (citation omitted).

For reverse payment cases, the Supreme Court has explicitly endorsed a no-payment agreement alternative. *Actavis*, 133 S. Ct. at 2236-37 (parties "may . . . settle in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior that point."); *Lamictal*, 791

F.3d at 403 (quoting *Actavis*); *Lidoderm*, 2017 WL 5068533, at *11-13, *30-32; *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp. 3d 734, 757 n.37 (E.D. Pa. 2015) ("*Wellbutrin*") (an alternate settlement scenario "is one mechanism through which the plaintiffs may establish anticompetitive effects at the summary judgment stage").[7] And the no-payment alternative must be based on an **objective evidentiary standard** – in this instance, what lawful, economically rational, profit-maximizing companies would have done. *See In re Nexium (Esomeprazole) Antitrust Litig.*, 842 F.3d 34, 60-61 (1st Cir. 2016) ("the test here is an objective test."); *Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc.*, 773 F.2d 1506, 1511 (9th Cir. 1985) (plaintiffs "must presume the existence of rational economic behavior in the hypothetical free market"); *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) (a "reasonable jury could not . . . indulge in the assumption that a competitor would follow a course of behavior other than that which it believed would maximize its profits.").; *Lidoderm*, 2017 WL 5068533, at *12, *24.

For example, in *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, Nos. 1:00-1898, MDL 1358 (SAS), M21-88, 2008 WL 1971538, at *11 (S.D.N.Y. May 7, 2008), the court credited plaintiffs' expert's opinion that the parties would have entered into alternative hypothetical contracts because it "would have been economically rational." *Cf. Laumann v. NHL*, 117 F. Supp. 3d 299, 324 (S.D.N.Y. 2015) (crediting expert analysis that in a but for world prices would "settle to a competitive, profit-maximizing equilibrium").

[7] The literature is in accord. *See* ABA Section of Antitrust Law, *Proving Antitrust Damages: Legal and Economic Issues*, 54-55 (2d ed. 2010) ("To isolate the effect of the violation . . . it is important to modify the defendants' conduct in the but-for world only to the extent necessary to comply with the law."); Areeda & Hovenkamp, IIA *Antitrust Law* ¶¶394 (3d ed. 2007) (to determine injury, "the plaintiff's actual profits are compared to what they would have been but for the antitrust violation"); Aaron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *The Actavis Inference*: *Theory and Practice*, 67 Rutgers U.L. Rev. 585, 609 (2015) (recognizing "an alternative settlement that did not have a large payment" as an available benchmark to model effects of generic delay).

Providing a but-for entry date without a reverse payment is explicitly envisioned in *Actavis* as an "approach[] [that is] fully consistent with the principles applied in but-for damage calculations" – namely, that it must be presumed in constructing a but-for world that the parties would engage in "rational economic behavior." *Lidoderm*, 2017 WL 5068533, at *12 (citing *Dolphin Tours, Inc.*, 773 F.2d at 1511 and *Murphy Tugboat Co.*, 658 F.2d at 1262). *See also In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 2008 WL 1971538, at *11; *Laumann*, 117 F. Supp. 3d at 324; *Kamerman v. Steinberg*, 744 F. Supp. 59, 63 (S.D.N.Y. 1990) (plaintiffs' reliance on circumstantial evidence failed because it ran counter to a "rational profit-maximizing approach"); *FTC v. Foster*, 2007 U.S. Dist. LEXIS 47606, *103 (D.N.M. May 29, 2007) (disapproving a theory that *failed* to presume that firms act in profit maximizing ways).

Despite *Actavis's* explicit guidance, Forest self-servingly claims it would have never agreed to such an earlier entry date. Def. Br. at 41-44. Defendants' argument, however, assumes away the key factual question the jury must answer – whether Mylan agreed to the 2015 entry date *because of* the additional inducement (payment) Mylan received. *See Lamictal*, 791 F.3d at 405 ("when the parties' settlement includes a [payment], the generic also presumably agrees to an early entry date that is later than it would have otherwise accepted."); *Niaspan*, 42 F. Supp. 3d at 751-52 (a reverse payment "is likely to induce the generic to agree to enter the market at a date later than that to which it would otherwise agree"). It also impermissibly exploits Forest's own wrongful conduct to its advantage:

> Where the tort itself is of such a nature as to preclude the ascertainment of the amount of damages with certainty, it would be a perversion of fundamental principles of justice to deny all relief to the injured person, and thereby relieve the wrongdoer from making any amend for his acts. In such case, while the damages may not be determined by mere speculation or guess, it will be enough if the evidence show the extent of the damages as a matter of just and reasonable inference, although the result be only approximate. The wrongdoer is not entitled to complain that they cannot be measured with the exactness and precision that would be possible if the case, which

he alone is responsible for making, were otherwise.

Story Parchment Co. v. Paterson Parchment Paper Co., 282 U.S. 555, 563 (1931); *see also Bigelow*, 327 U.S. at 265.

With the *Story Parchment* and *Bigelow* principles in mind, the but-for-world – a construct necessitated by the antitrust violators' perversion of free market conditions – is devised with objective evidence. [redacted]

Forest's reliance on *Wellbutrin* is misplaced. The district and appellate courts in *Wellbutrin* actually *agreed* that an alternate settlement scenario can support causation; however, they found the evidence there insufficient to support the theory. Specifically, unlike here, the expert in that case "offer[ed] no testimony in support of a contention that an alternate settlement would have been reached" and "did not '[try] to answer the question of what specifically some alternative form of settlement would have looked like." *Wellbutrin*, 133 F. Supp. 3d at 757-58. Thus, this case,

[8] *See, e.g.*, *Castro v. Sanofi Pasteur Inc.*, 134 F. Supp. 3d 820, 830 (D.N.J. 2015) (Prof. Elhauge is "a preeminent antitrust scholar" who is "eminently qualified" on antitrust economics and has "been described as a 'highly qualified antitrust titan.'"); *In re Mushroom Direct Purchaser Antitrust Litig.*, No. 06-0620, 2015 WL 5767415, at *4 (E.D. Pa. July 29, 2015) ("courts have admitted Prof. Elhauge as an expert in antitrust economics generally . . . Prof. Elhauge has been described as a 'highly qualified antitrust titan[].'") (citation omitted).

like *Lidoderm*, is distinguishable from *Wellbutrin*. *Lidoderm*, 2017 WL 5068533, at *10 (stressing that *Wellbutrin* accepted the but-for no-payment settlement method for proving causation). In *Lidoderm*, Judge Orrick pointed out that the *Wellbutrin* decisions only rejected the no-payment settlement method on the facts of *Wellbutrin*, because it was not supported by any expert testimony, unlike here, as explained above. *Id*. at *12 (Prof. Elhauge's "analys[i]s – applying accepted principles of antitrust law and settlement analysis to evidence in this case – [is] different than what happened in *Wellbutrin*").

Moreover, the *Wellbutrin* facts differ significantly from those here. First, the settlement in *Wellbutrin* allowed the underlying patent litigation to continue – a fact that the court considered a "critical distinction." *Wellbutrin*, 133 F. Supp. 3d. at 737-38, 752. The court held that "[t]the plaintiffs…cannot establish that the Wellbutrin settlement presented the type of anticompetitive harm contemplated by *Actavis* and *Lamictal* because the settlement did not induce the generic manufacturer to quit its patent challenge and thus did not eliminate the risk of patent invalidation or a finding of non-infringement by the court." *Id*. at 754 (internal quotations omitted). Second, three separate companies owned patents that purported to cover Wellbutrin – GSK, Biovail, and Andrx. *Id*. at 740, 743. Plaintiffs in *Wellbutrin XL* would have had to show not only that the generics would have prevailed in litigation against (or reached an agreement for earlier entry with) GSK and Biovail, but that Andrx would have subsequently agreed to license its patent to the generics. *Id*. at 747-48. That is because plaintiffs in *Wellbutrin* did "not even argue that the generic manufacturers could have succeeded in the Andrx litigation." *Id*. at 767.

There is further evidence that Forest and Mylan would have entered into a no-payment settlement agreement with an earlier launch date. Specifically, the settlements with all the prior Namenda patent defendants included various contingent launch provisions that licensed them to

enter should a later settler negotiate an earlier entry date. PASoF ¶204(6). Thus, Forest and the Namenda patent defendants clearly envisioned a subsequent settlement earlier than three months prior to patent expiry. Forest witnesses testified that these clauses had "value" to the generics (DSoF ¶351), which would only be true if earlier launch was reasonably probable.

[redacted]. *See* PASoF ¶¶228-33, 235-38, 240, 244.

Defendants, on the other hand, support their argument *only* with *post-hoc* testimony of their own employees. Given that Forest and Mylan decided to settle *with* a large reverse payment, they unsurprisingly now claim they would not have settled without one. But the jury is not required to believe them. Also, Forest's employees were ***not*** asked whether *without Forest making a reverse payment*, Forest would have agreed to an earlier entry date. Def. Br. at 41-42.

ii. Plaintiffs Have Sufficient Evidence to Prove That Mylan Would Have Prevailed in the Patent Case

Forest argues that Plaintiffs "cannot establish causation and antitrust injury by reference to a hypothetical patent trial between Forest and Mylan." Def. Br. at 45. But this Court has already endorsed such a theory, stating that if Forest had "lost the litigation, the patent would have been declared invalid or not infringed and the Generic Competitors could have entered the market immediately." Litvin Decl. Ex. 355, Estoppel Op. at 37. This Court further held that Plaintiffs' Section 1 claim "will presumably require proof that the '703 Patent would likely have been found invalid or not infringed by the Generic Competitors[.]" *Id.* at 40. Plaintiffs have that evidence.

Rather than address the patent merits as Plaintiffs do here, however, Forest asks this Court to rule that the flurry of settlements following claim construction establish that, as a matter of law,

Mylan could not have prevailed. Neither the *Markman* ruling nor the flurry of settlements – particularly viewed in the light most favorable to Plaintiffs – supports Forest's position. As Forest explained to Mylan during settlement discussions, "[e]very other ANDA filer has recognized that there is no ***financial*** upside to litigating." PASoF ¶¶56-57; PRSoF ¶294. This had nothing to do with the patent merits, but rather that there were fourteen first-filers who would "share [the] 180-day exclusivity" and that "sales and profits for generic memantine [were going to] be miniscule" as a result. *Id*. When the patent court issued its *Markman* ruling, the generics' prospects for a ***quick*** victory were greatly reduced. A reasonable jury could conclude that the generics' settlements did not reflect concerns about the patent merits, but that the "miniscule" economic "upside" from successful suit did not justify the "downside" of large litigation costs.

a. Mylan Was Likely to Prove That the '703 Patent Is Invalid

A reasonable jury could readily conclude that Mylan was likely to prevail on its prior art invalidity defenses. Forest's sole argument that "the PTO already considered" the prior art (Def. Br. at 48) ignores settled law that "[t]he courts are the final arbiter of patent validity and, although courts may take cognizance of . . . the proceedings before the patent examiner, the question is ultimately for the courts to decide, without deference to the rulings of the patent examiner." *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 876 (Fed. Cir. 1991).

There is nothing novel or non-obvious about the '703 patent claims. For many years before filing the '703 patent, Merz sold memantine tablets in Europe under the name Akatinol® to treat patients diagnosed with organic brain syndrome ("OBS"). PASoF ¶¶36-40. OBS "is synonymous with what neurologists refer to as Alzheimer's disease." PASoF ¶38. Merz then licensed Forest to sell the same drug product in the United States to treat essentially the same disease (Alzheimer's disease). PASoF ¶41. The original claims of the '703 patent were invalid in view of prior art

pertaining to Akatinol® and, in 2004, Forest sought reexamination. PASoF ¶42. The reexamined claims, however, added trivial limitations that also are undisputedly disclosed in the prior art including "*orally* administering" and "to a patient *diagnosed with Alzheimer's disease*." PASoF ¶42. (emphasis in original). In view of the prior art references pertaining to Akatinol® and the Fleischhacker reference that specifically disclosed administering memantine to patients diagnosed with Alzheimer's disease, the '703 patent was likely to be invalidated in the Namenda Patent Litigation, just as the foreign counterparts to the '703 patent had been in Germany and Canada. PASoF ¶¶42-50.[9] Plaintiffs' expert here, Dr. Schneider, is a leading clinician in the field of Alzheimer's disease and has reached the same conclusions as Mylan's experts regarding anticipation and obviousness. PASoF ¶51. Further, Forest's experts have conceded key points supporting the invalidity of the '703 patent claims. PASoF ¶¶46-48.

The '703 patent was also invalid for lack of enablement. The enablement requirement is not satisfied when there "is 'no indication that one skilled in [the] art would accept without question statements [as to the effects of the claimed drug products] and no evidence has been presented to demonstrate that the claimed products do have those effects." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005). During prosecution, Forest overcame an ***obviousness*** rejection by submitting a declaration to the Patent Office stating that "it was understood by Physicians that NMDA receptor antagonism could impair cognition" and that "the use of NMDA receptor antagonism in general . . . would have been contraindicated for the treatment of Alzheimer's disease in 1989 because it was thought that blocking of NMDA receptor function would result in reduced cognition and greater vulnerability to excitotoxicity." PASoF

[9] Any attempt to distinguish the prior art based on Forest's purported discovery of a new mechanism of action would have failed because the mechanism of action of memantine – whatever it is – would have also existed in the prior art. PASoF ¶50.

¶52. While this representation was helpful for purposes of overcoming the ***obviousness*** rejection, it was devastating for purposes of ***enablement*** because the '703 patent contains no studies on any humans, much less any studies suggesting that memantine can be used successfully for the treatment of Alzheimer's disease through NMDA receptor antagonism. PASoF ¶¶52-55. Thus, the '703 patent did not enable claims covering the use of memantine to treat Alzheimer's disease through NMDA receptor antagonism. *Id.*[10]

b. Mylan Was Likely to Prevail on Non-Infringement

A reasonable jury could also conclude that Mylan would prevail on non-infringement. Mylan pressed two such theories – only one of which Forest even acknowledges – for which Mylan's expert Dr. Olney offered compelling evidence and for which Forest's expert Dr. Doody made key admissions. PASoF ¶¶59-64. Under Mylan's non-infringement theories, the claim construction Forest touts became the albatross across its neck. Although the reexamination certificate for the '703 patent contains nineteen claims (three of which are independent), Mylan's non-infringement theories can be drastically simplified. The originally-issued '703 patent contained only one independent claim. PASoF ¶65. If that originally-issued independent claim was not infringed, then neither was any of the dependent claims. *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). Likewise, if that originally-issued

[10] The '703 patent claims also fail to satisfy the enablement requirement for an additional reason. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use ***the full scope of the claimed invention*** without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (emphasis added). Here, each of the claims covers a 10,000-fold memantine dose ranging from 0.01 mg/kg to 100 mg/kg. PASoF ¶54. But for purposes of attempting to prove infringement, Forest's own expert Dr. Malinow admitted that a "20 mg/kg of memantine . . . corresponds to around *4 times* the highest acceptable dose in humans" (*i.e.*, the "highest acceptable dose in humans" is 5 mg/kg). *Id.* ¶55 (emphasis in original). Thus, Dr. Malinow admitted that more than 95% of the dose range covered by the claims was not only not enabled, but completely unacceptable. *Id.* Forest has not meaningfully attempted to rebut this critical defect in the claims of the '703 patent.

independent claim was not infringed, then any ***infringed*** reexamined claim was necessarily invalid as having been improperly broadened. *Quantum Corp. v. Rodime, PLC*, 65 F.3d 1577, 1584 (Fed. Cir. 1995). Thus, this Court need only consider originally-issued claim 1.[11]

Originally-issued claim 1 was limited to a "method for the prevention or treatment of cerebral ischemia" and required "administering…an effective amount" of a class of compounds that included memantine. PASoF ¶73. The patent court's claim constructions relating to "prevention or treatment of cerebral ischemia" required that memantine achieve its therapeutic effects through NMDA receptor antagonism. PASoF ¶¶74-78. Mylan's expert Dr. Olney was an extremely highly regarded neurobiologist. PASoF ¶79. [redacted] PASoF ¶82.[12] These views – if accepted by the fact-finder – compelled a conclusion of non-infringement.

A reasonable jury could also conclude that, even if memantine acted as an NMDA receptor antagonist at the relevant doses, Forest could not meet its burden of proving that Mylan's [redacted] was an "effective amount." This term was construed by the patent court to mean "an amount shown to cause improvement, in comparison to placebo." PASoF ¶74.

[11] Plaintiffs have nevertheless marshaled substantial evidence from which a reasonable juror could also conclude that none of the reexamined claims was infringed. PASoF ¶¶66-72.

[12] Moreover, Forest overlooks that, if Mylan obtained a reversal of the patent court's claim construction ruling, Mylan would prevail on non-infringement as a matter of law because [redacted]. PASoF ¶58.

The sole evidence relied upon by Forest's expert to establish that Mylan's proposed memantine dose was an "effective amount" [redacted]. PASoF ¶64. At her deposition, Forest's expert in the underlying patent case, Dr. Doody, admitted that this clinical study provided no evidence of memantine's mechanism of action or whether there was any improvement in "the treatment or prevention of cerebral ischemia" as the claim required. PASoF ¶¶64, 74-78. Mylan's expert Dr. Olney opined that [redacted]. PASoF ¶63. Indeed, Dr. Olney's evidence showed that [redacted]. PASoF ¶83.

Plaintiffs' evidence confirms Mylan's non-infringement defenses. Plaintiffs' expert, Dr. Herrmann, is a leading researcher in the field of Alzheimer's disease and has reached virtually the same conclusions as Dr. Olney regarding non-infringement. PASoF ¶84. And Forest's own experts admitted key points undermining Forest's infringement theory. PASoF ¶¶85-86. For example, Dr. Malinow testified that the relevant dose of memantine "provides a neuroprotective effect by antagonizing NMDA receptors." *Id.* But he admitted that "neuroprotection would cause slowing of neurodegeneration." *Id.* The FDA-approved Namenda label states that "[t]here is no evidence that memantine prevents or slows neurodegeneration in patients with Alzheimer's disease." *Id.* ¶86. Thus, Forest's own label confirms that there is "no evidence" that memantine is functioning as an NMDA receptor antagonist at the relevant doses.

c. Mylan Was Likely to Prevail on its PTE Validity Challenge

At trial, the jury could further determine that Mylan was more likely than not to prevail on its challenge to the validity of Forest's PTE. Under 35 U.S.C. § 282, "[i]nvalidity of the extension

of a patent term or any portion thereof" may be based on "the material failure . . . by the applicant for the extension . . . to comply with the requirements of [35 U.S.C. § 156]." During the PTE proceeding, Forest claimed a 1,250 day extension based on a "testing phase" that began in 1997. PASoF ¶98. However, FDA viewed the "testing phase" as beginning in 1990, and PTO ultimately awarded a 5-year PTE. PASoF ¶¶99-116. Forest committed two material failures in connection with its request for a PTE. First, Forest failed to declare the number of days during the expanded "testing phase" when there was a failure to act with due diligence. PASoF ¶¶100-02, 106, 109. Second, Forest failed to provide a chronology of studies over the expanded "testing phase." PASoF ¶¶102-03, 109. Forest's own experts, Mssrs. McKelvie and Rosen, do not dispute that these were material failures under the statute. PASoF ¶110. Rather than address these material failures, Forest introduces a "red herring" – that FDA's due diligence determination under § 156(d)(2) is not reviewable in a patent infringement trial. *See* Def. Br. at 49; 35 U.S.C. § 282(c).

[redacted] There is no legitimate dispute that those material failures of section 156 are a defense in a patent infringement trial. 35 U.S.C. § 282(c).[13]

d. Mylan's Likelihood of Success in the Patent Litigation

A reasonable jury could also conclude that Mylan was more likely than not to prevail based upon the testimony of patent litigation experts. Plaintiffs' expert, Mr. Johnston,[14] is a former Chief

[13] As previously explained, this claim supports injunctive relief to invalidate the extended term of the patent, but not damages, which Mylan conceded would not even begin to accrue until more than three years after the Namenda patent settlement was reached.

[14] As explained in more detail in DPP's concurrently filed Opp'n to Forest's Mot. to exclude Mr. Johnston (ECF No. 443), Mr. Johnston's testimony on how a reasonable patent attorney would

Patent Counsel at Roche Pharmaceuticals, Inc. who routinely handicapped patent litigation during his 30-year tenure at the company. PASoF ¶87. After a detailed analysis of Mylan's invalidity and non-infringement defenses, he concluded that a reasonable patent attorney would conservatively conclude that Mylan had a greater than [redacted] chance of prevailing on liability issues in the Namenda Patent Litigation and a [redacted] chance of prevailing on the PTE issue. PASoF ¶¶88-89.[15] A reasonable juror could conclude that, based on Mr. Johnston's expert handicapping of the case, Mylan was more likely than not to prevail.

e. The Pediatric Exclusivity Provision Was Anticompetitive

Forest argues that Plaintiffs' "pediatric exclusivity allegation rises or falls on the issue of whether there was a large and unjustified reverse payment . . . that caused delay" and that Plaintiffs have not met their burden on this issue. Def. Br. at 50. This argument fails because it grossly misstates the evidence in the case. As set forth *infra*, Plaintiffs have adduced significant evidence and will prove that the [redacted] payment to Mylan was large and unjustified. *See* Part III.A, *supra*. Moreover, Plaintiffs' economic expert explains in his report, using robust mathematical calculations of the bargaining strength of the parties during settlement negotiations, that the reverse

objectively view the parties' likelihoods of success is necessary because Forest has consistently claimed privilege on its *subjective* beliefs on the merits. *E.g.*, Forest Disclosure Pursuant to the May 19, 2017 Order at 5 ("Forest does not intend to affirmatively rely on its subjective beliefs to rebut any argument that (1) its position in the patent case was weak…."). Forest now reneges by relying upon testimony from its Chief IP attorney that Forest believed it "had a very strong case." Def. Br. at 50, 39. The Court should disregard this testimony.

[15] Defendants' expert, Mr. McKelvie, opined that Forest was "more likely than not" to win on each of Mylan's eight defenses, and would not testify that Forest's chances were any higher than that. PASoF ¶90-91. But he admitted that Mylan would prevail if it won on any *one* of those eight defenses. *Id.* ¶92. Even assuming Forest's likelihood of prevailing on each of those defenses was 75%, Forest's chances of running the table on each – as it was required to do to prevail – was far less than 50%. *See Wellbutrin*, 868 F.3d at 169 n.61 (recognizing that likelihood of success overall requires multiplying odds of success on different defenses for which patent holder must prevail). Thus, Defendants' own expert effectively concedes that Mylan was more likely than not to win.

payment to Mylan delayed the generic entry date by [redacted]. PRSoF ¶¶332, 354; O'Shaughnessy Decl. Ex. 121, Elhauge Report ¶ 2. Finally, Plaintiffs have adduced significant evidence that, absent the anticompetitive delay, four or more generic competitors (including Mylan) would have launched their generic Namenda products years earlier than they actually did, and that Forest would have concurrently launched an AG. PASoF ¶¶117-99; PRSoF ¶¶333-36; Litvin Decl. Ex. 343, Thomas Report ¶¶7-8; O'Shaughnessy Decl. Ex. 356, DeLeon Report ¶¶10-11. Forest also ignores a "but for world" where there is no settlement – in which case the generics who received final approval prior to the expiration of the patent could all market their generic Namenda products without regard to Forest's Pediatric Exclusivity. Litvin Decl. Ex. 343, Thomas Report ¶¶126-127, 129-131, 134-135, 318-319, 142-144; O'Shaughnessy Decl. Ex. 356, DeLeon Report ¶¶10, 123-25. Consequently, the Pediatric Exclusivity issue is a question for the jury.

Furthermore, the prospect that some generic companies, including Mylan, would have entered the market "at risk" was explicitly recognized by Forest and the settling generic companies in the contingent launch provisions of the respective patent settlement agreements. As discussed above, these provisions allowed for earlier entry by a settling generic should a non-settling generic enter the market in any one of three ways, including "at risk." Forest has admitted that these early entry provisions were demanded by the generics, were valuable to them, and fostered earlier generic competition. Forest is correct – the early launch provisions were valuable because it was reasonably probable that Mylan, the last of the settling generics, would enter the market "at risk" absent being paid to delay its market entry.

C. Forest's Hard Switch Efforts Caused Plaintiffs to Sustain Antitrust Injury

1. Standard for Proving Injury and Damages

Contrary to Forest's argument, controlling Supreme Court law requires a plaintiff to show only that illegal conduct is "a material cause of the injury; a plaintiff need not exhaust all possible

alternative sources of injury in fulfilling his burden of proving compensable injury" under section 4 of the Clayton Act. *Zenith Radio Corp. v. Hazeltine Res., Inc.*, 395 U.S. 100, 114 n.9 (1969). The Second Circuit has explained this means "an antitrust defendant's unlawful conduct need not be the sole cause of the plaintiffs' alleged injuries; to prove a 'causal connection' between the defendant's unlawful conduct and the plaintiff's injury, the plaintiff need only 'demonstrate that [the defendant's] conduct was a substantial or materially contributing factor' in producing that injury." *In re Publ'n Paper Antitrust Litig.*, 690 F.3d 51, 66 (2d Cir. 2012) (emphasis and alteration in original) (quoting *Litton Sys., Inc. v. AT&T Co.*, 700 F.2d 785, 823 n.49 (2d Cir. 1983)); *Actos*, 848 F.3d at 97 ("defendant's anticompetitive act" need not be "sole cause" of plaintiffs' injury). *See also* Litvin Decl. Ex. 355, Estoppel Op. at 33 ("plaintiff need only show that the illegal conduct 'was a substantial or materially contributing factor' to its injuries.'") (quoting *Litton*, 700 F.2d at 823 n.49). Further, "an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct 'is deemed wrongful because it is believed significantly to increase the risk of a particular injury' and that injury occurred." *Actos*, 848 F.3d at 101 (quoting *Publ'n Paper*, 690 F.3d at 66). And, as noted above, the causation issue is left to the jury. *See* Part III.B.1., *supra*.

As noted above, the Supreme Court has long recognized that a defendant should not be able to benefit from the uncertainty that its own conduct has produced. *See* Part III.B.1, 2 *supra*. Thus, once the fact of injury is shown, damage "calculations need not be exact." *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013). *See also LePage's Inc. v. 3M*, 324 F.3d 141, 166 (3d Cir. 2003) ("Once a jury has found that the unlawful activity caused the antitrust injury, the damages may be determined without strict proof of what act caused the injury, as long as the damages are not based on speculation or guesswork."). *See also* Direct Purchaser Class Plaintiffs'

Mem. in Opp'n to Forest's Mot. to Exclude Dr. Russell Lamb ("Lamb *Daubert* Opp'n"), filed contemporaneously herewith (discussing applicable law of proving injury and damages).

2. Plaintiffs Have Demonstrated that Forest's Hard Switch Strategy was a Substantial Factor in Causing Harm to Plaintiffs

Plaintiffs adduce abundant proof that Forest's lengthy promotional blitz of its hard switch was a "materially contributing factor," *Publ'n Paper*, 690 F.3d at 66, in causing direct purchasers to buy more Namenda XR – at supracompetitive prices – than they would have otherwise.

As Judge Sweet found, and as Forest is estopped from contesting, "the purpose of the switch was anticompetitive: to put barriers obstacles in the path of producers of generic memantine and thereby protect Namenda's revenues from a precipitous decline following generic entry." O'Shaughnessy Decl. Ex. 6, Unredacted Sweet Op. at 119. *See also* PASoF ¶¶30-33 (citing testimony from Forest executives that generics would take [redacted] or more of brand sales within months of entry). Judge Sweet extensively cited Forest's own forecasts detailing the expected impact of its hard switch strategy. This Court reiterated Judge Sweet's findings that "a 'significantly higher' number of patients would convert from Namenda IR to Namenda XR than if Forest had not attempted to pull Namenda IR from the market and that *"Forest's own internal projections estimated that, using only soft-switch tactics, only* [redacted] *of Namenda IR patients would voluntarily switch to Namenda XR."* PRSoF ¶488 (quoting Estoppel Op. at 24) (emphasis added). The record here confirms that Forest prepared a series of forecasts predicting that its "soft switch" strategy would convert only approximately [redacted] of branded Namenda IR sales to Namenda XR before generic entry. PASoF ¶¶301-19; PRSoF ¶¶388-90, 396, 464. However, Forest was not meeting its conversion goals using "soft switch" tactics alone; at one point Forest noted it was struggling to "meet our FY14 goal of [redacted]," and that it was not gaining share as expected in the Long Term Care market. PASoF ¶¶320-22. By October 2013, conversion to Namenda XR had

plateaued, PASoF ¶¶323-30, and Forest decided to pursue its hard-switch strategy to withdraw Namenda IR from the market. PASoF ¶¶331-35. Forest began communicating its hard switch decision in October 2013 to managed care to obtain more favorable formulary placement for Namenda XR, accelerating conversion. PASoF ¶340; PRSoF ¶373. *See also* Plaintiffs' Opp'n to Mot. to Exclude Opinions of Dr. Lamb at 18-19 ("Lamb *Daubert* Opp'n"), filed contemporaneously herewith.

Following the February 14, 2014 hard switch announcement and the marketwide promotional blitz about withdrawal, Forest was able to artificially boost the conversion rate to at least [redacted] – far greater than was expected via soft switch tactics. As this Court held:

> Importantly, Judge Sweet found that Forest's hard-switch tactics had already resulted in more customers converting from Namenda IR to Namenda XR than Forest had estimated would convert voluntarily. At the time the preliminary injunction was entered, "about [redacted] of existing patients [had] converted from Namenda IR to Namenda XR in anticipation of the lack of availability of Namenda IR." This is significantly more than the [redacted] that Forest had estimated would convert if only soft-switch tactics were employed.

PRSoF ¶488 (quoting Estoppel Op. at 25) (internal citation omitted). These findings are binding.

Drs. Berndt and Lamb confirmed and expanded upon these findings through detailed analyses. Dr. Berndt examined the content and evolution of Forest's forecasting of its IR/XR conversion using just soft switch tactics. He observed that with real-world experience following Forest's June 2013 launch of Namenda XR, Forest recognized that using soft switch tactics alone, it would achieve only about [redacted] conversion for Namenda XR. Dr. Berndt concluded these internal forecasts were reliable for the economic analysis performed by Dr. Lamb. O'Shaughnessy Decl. Ex. 231, Berndt Report ¶40. *See also* O'Shaughnessy Decl. Ex. 55, Berndt Reply ¶¶4-20. Using such forecasts, Dr. Lamb modeled what would have happened absent the hard switch tactics. Dr. Lamb relies on Forest's own post-XR-launch forecasts (the same sort of forecasts Judge Sweet

relied upon), and Forest's adoption of those forecasts in internal discussions among high-level executives (including Forest's Board) to arrive at an expected estimated [redacted] conversion rate from IR to XR, in the absence of the wrongful "hard switch." O'Shaughnessy Decl. Ex. 193, Am. Expert Report of Dr. Russell L. Lamb ("Lamb Report") ¶¶151-54; O'Shaughnessy Decl. Ex. 56, Am. Exp. Reply Rep. of Dr. Russell L. Lamb (Nov. 9, 2017) ("Lamb Reply") ¶¶30-36, 42, 97. Dr. Lamb focused on "forecast documents that were created after Namenda XR had entered the market and before the Hard Switch was implemented" and which included an expected generic IR entry date of July 2015 (as actually occurred) to compute the but-for conversion rate. Lamb Report ¶152 (including table showing soft switch conversion rates in eight separate Forest forecasts). After reviewing this evidence, Dr. Lamb compares the but-for sales that Namenda XR would have gotten absent Forest's illegal hard switch with the artificially inflated sales Namenda XR did achieve. *Id.* ¶¶143-56.

Importantly, Forest's forecasts that Dr. Berndt and Dr. Lamb analyzed contained both a "withdrawal" (or "hard switch") scenario *and* a "conventional" (or "soft switch") scenario, as well as internal high-level discussions of, and reliance upon, these forecasts to reach conclusions about what the conversion rate from Namenda IR to XR would have been absent the hard switch strategy. Thus, Forest's own forecasts of the effects of a soft switch – including detailing to physicians and lobbying health plans to cover XR – as compared to a hard switch demonstrate the incremental effect on the rate of conversion of the hard switch. *See* PASoF ¶312, 396; PRSoF ¶¶463-64, 478.

These documents were prepared contemporaneously with the decision to engage in the hard switch in 2013, and were relied upon by Forest to estimate the expected incremental effects of a possible hard switch strategy – over and above a soft-switch-only approach – and the ability of a hard switch to limit the "patent cliff" effects associated with generic entry. These documents –

admissions by Forest of the effects of its hard switch – provide a reliable basis to estimate what would have happened had Forest not embarked on its anticompetitive hard switch strategy.

Moreover, Forest's documents reveal [redacted] *See* O'Shaughnessy Decl. Ex. 193, Lamb Report ¶¶93-97 & Fig. 6; PASoF ¶¶402, 370; PRSoF ¶464 (citing Forest documents that in [redacted]). Thus, Forest's own analyses [redacted]." *See, e.g.*, PRSoF ¶464. This was borne out in practice, as evidenced by the deposition of Dr. Lah, a neurologist who treats a large Alzheimer's patient population, and who testified in the New York Attorney General action that "knowing that Namenda IR would no longer be available past a certain date, we began switching patients from Namenda IR to Namenda XR." PASoF ¶¶348, 369.

Moreover, Forest understood that once physicians got into the habit of writing Namenda XR prescriptions, they would likely maintain that habit, because as Forest itself stated: "[redacted]," and Forest not only widely broadcast its plan to withdraw IR, it averred to the Second Circuit that it had stopped manufacturing IR (before the injunction) "[redacted]." PRSoF ¶¶412, 397. Once converted, physicians would continue to prescribe Namenda XR for all of their patients, even after Namenda IR became available. *See* PRSoF ¶¶359, 412, 472; O'Shaughnessy Decl. Ex. 56, Lamb Reply ¶¶87, 90, 93; O'Shaughnessy Decl. Ex. 55, Berndt Reply ¶18.

In addition, Forest's hard switch communications strategy was not limited to the announcement on February 14, 2014. Rather, Forest aggressively, repeatedly, and widely

publicized the hard switch to physicians, caregivers, pharmacies, and health plans in advance of the planned August 2014 withdrawal, and Dr. Lamb reviewed evidence confirming that the publicity affected prescriptions in advance of the threatened withdrawal. *See* PASoF ¶¶365-68; PRSoF ¶373; *see also* O'Shaughnessy Decl. Ex. 193, Lamb Report ¶¶98-105; O'Shaughnessy Decl. Ex. 55, Berndt Reply ¶25.

Forest's own citations agree that all that is required is that "damages awarded must be traced to some degree to unlawful acts." *U.S. Football League v. Nat'l Football League*, 842 F.2d 1335, 1378 (2d Cir. 1988). But they are off-point in other respects. In *U.S. Football*, the plaintiff obtained only nominal damages after trial (it did not lose on summary judgment), and the Second Circuit affirmed because the defendant offered "much evidence" that plaintiffs' "self-destructive" business decision, not alleged anticompetitive conduct, led to the injury, *id.* at 1377, quipping that "[c]ourts do not exclude evidence of suicide in a murder trial." *Id*. at 1370. In Forest's other cases, plaintiffs failed to "show *any* form of causality[.]" *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc*., 375 F. 3d 1341, 1365 (Fed. Cir. 2004) (emphasis added); *see also Ashley Creek Phosphate Co. v. Chevron USA, Inc*., 315 F. 3d 1245, 1252, 1260 (10th Cir. 2003) (plaintiff "ha[d] simply not put forward even a scintilla of evidence to demonstrate that it suffered any [antitrust] harm to its property at the hands of [defendant].").

3. Plaintiffs' Injury Model Is Consistent with This Court's Prior Opinions

Defendants use a pastiche of out-of-context quotes to conjure a supposed three-part test for proving injury. Def. Br. 57-58. *Cf.* Lamb *Daubert* Opp'n at 16-18 (detailing how Defendants have mischaracterized this Court's motion to dismiss opinion). In Defendants' motion to dismiss, they argued that Plaintiffs could not demonstrate any injury. *See* Mot. to Dismiss, ECF No. 57 at 30. In rejecting that argument, the Court recognized one theory of alleged injury. MTD Op., 2016

WL 4992690, at *12. But the opinion in no way set outer boundaries on what types of injuries direct purchasers can prove – particularly as the Plaintiffs did not have occasion to argue these points on the motion to dismiss, and there was no evidentiary record before the Court. *See Schwabenbauer v. Bd. of Educ.*, 777 F.2d 837, 842 (2d Cir. 1985) (issue not briefed or argued previously and not necessary to resolution is dicta and does not bind court). The Court, for instance, did not have occasion to address Plaintiffs' allegation that injuries continued past the injunction and past generic entry. *See* Pls.' Compl., ECF No. 26, ¶¶226-29.

Since then, Plaintiffs have developed robust evidence to demonstrate the injury caused by the hard switch campaign, including the evidence of Forest's lengthy and pervasive post February 14, 2014 actions to convince physicians, caregivers, health care plans and the rest of the market that Namenda IR would be discontinued with the purpose, intent, and effect of influencing the decision making and habits of physicians to convert to Namenda XR. As shown below, while Judge Sweet ordered Forest to keep Namenda IR on the market until shortly after generic entry in July 2015 and to send out some communications regarding his injunction, the record demonstrates that Forest's post-injunction conduct was no cure. Forest's communications about the injunction were far more limited than the pervasive messaging about the withdrawal, and were tainted with Forest's vow that it was appealing the ruling, leaving fear, uncertainty and doubt about Namenda IR's continued availability.

4. Plaintiffs Do Not Need to Trace Switching at a Patient Level

It is unnecessary to trace the effects of a "hard switch" to individual patients to establish injury to direct purchasers. The Plaintiffs here are direct purchasers, not patients or health plans. PRSoF ¶458. Two pharmaceutical antitrust cases have addressed – and soundly rejected – Forest's proposal. In *In re Warfarin Sodium Antitrust Litigation*, 214 F.3d 395 (3d Cir. 2000), a class of

purchasers brought antitrust claims against DuPont for suppressing generic competition to Coumadin. The *Warfarin* plaintiffs alleged that "DuPont, anticipating a loss of market share resulting from the introduction of a cheaper generic substitute for Coumadin, orchestrated a campaign disparaging generic substitutes." *Id*. at 397. The net effect (like a product hop) was not to bar generic entry, but "to disable its market penetration," and as a result "due to DuPont's effort to derail generic competition, [individual purchasers] have paid inflated prices for Coumadin." *Id*. DuPont, like Forest here, argued that plaintiffs had to show that individual patients were deceived, but the Third Circuit, affirming class certification, disagreed:

> [P]laintiffs have alleged that DuPont engaged in a broad-based campaign, in violation of federal and state consumer fraud and antitrust laws, to deceive consumers, TPPs, health care professionals, and regulatory bodies into believing that generic warfarin sodium was not an equivalent alternative to Coumadin…
> [P]roof of liability does not depend on evidence that DuPont made deceptive communications to individual class members or of class members' reliance on those communications;… the fact that plaintiffs allege purely an economic injury as a result of DuPont's conduct (i.e., overpayment for warfarin sodium), and not any physical injury, further supports a finding of commonality and predominance because there are little or no individual proof problems in this case.

In re Warfarin Sodium Antitrust Litig., 391 F.3d 516, 528-29 (3d Cir. 2004) (emphasis added).

In *TriCor*, another "hard switch" product hop case, the court also rejected the same impact theory Forest advocates. The defendants argued that "even if TriCor prices would have been lower in the 'but for' world, it is impossible to determine, through class-wide proof, which class members would have continued to purchase TriCor rather than switching to a still lower priced generic fenofibrate or some other [] therapy." *Teva Pharm. USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 229 (D. Del. 2008) ("*TriCor*"). The court rejected this theory. "[D]irect purchaser plaintiffs only are required to show that they, in fact, did purchase TriCor at a higher price once an antitrust violation and causal relationship are established." *Id.* at 230-31 (footnote and citations omitted).

In this light, and in view of the fact that direct purchasers stock products in anticipation of

customer demand, this Court's observation that Plaintiffs' proof of injury may involve showing "patients switched to Namenda XR because of the announced withdrawal of Namenda IR," MTD Op., 2017 WL 4992690, *12, requires nothing more than, as indicated in *Warfarin* and *TriCor*, proof that the volume of Namenda XR purchases by Plaintiffs (wholesalers) exceed the volume of Namenda XR purchases that would have been made had Forest engaged in soft-switch tactics alone. Plaintiffs have done precisely that, demonstrating that Forest expected it could capture only approximately [redacted] of the market without the illegal, hard switch tactics.

Despite Defendants' contentions to the contrary (Def. Br. at 58), Dr. Lamb's damage model does exclude damages not attributable to the hard switch strategy. *See* PRSoF ¶¶464-94. Indeed, Dr. Lamb's analysis only re-confirms this Court's prior conclusion that Forest's own expectation of what the conversion would be absent the hard-switch ([redacted]) was reasonable. *See* Litvin Decl. Ex. 355, Estoppel Op. at 24-25 (citing *New York v. Actavis, PLC*, No. 14 CIV. 7473, 2014 WL 7015198, at *80, 109-11 (S.D.N.Y. Dec. 11, 2014)). While Defendants cite Dr. Lamb's testimony that he did not *directly* test whether a particular individual switched because of the hard switch strategy, Dr. Lamb's analysis – incorporating defendants' own forecasts, National Sales Perspectives data from IMS, and manufacturer data – reliably measures what ultimately matters here: the incremental effect of the hard switch on purchases by wholesalers, and this measurement necessarily reflects the increased conversion by patients. PRSoF ¶¶460-62. Dr. Lamb confirmed at his deposition that physicians or patients "who prefers some aspect of… Namenda XR would be accounted for under the patients that switched in the but-for world in the soft switch strategy." PRSoF ¶460. Dr. Lamb thus correctly rejected the suggestion his "damages analysis doesn't account for the fact that there are some physicians or patients who might have some preference for Namenda XR for whatever reason." *Id.*

And although Defendants fault Dr. Berndt for not conducting a regression or econometric analysis, Def. Br. at 60, *Dr. Lamb* does precisely this, conducting a structural break test (a form of regression analysis based on IMS National Sales Perspective data) that reveals a statistical difference in the rate of conversion to Namenda XR before and after the widespread February 2014 announcement of the hard switch campaign for nearly all purchasers who bought monthly from June 2013 through June 2015. *See* PRSoF ¶468. Thus, Dr. Lamb supports his reliance on Forest's forecasts with an econometric analysis based on data completely independent of those forecasts.

As Plaintiffs' damage models account for other conduct which may have caused purchases of Namenda XR not attributable in part to the hard switch strategy, Defendants' cases (Def. Br. at 60-61) are distinguishable. *See, e.g., Gatt Commcn's, Inc. v. PMC Assocs., L.L.C.*, 711 F. 3d 68, 74, 77-78 (2d Cir. 2013) (plaintiff "had identified neither a relevant product market nor an adverse effect on competition in *any* market[,]" "it was not clear the underlying conduct is prohibited by the antitrust laws[,]" and any injuries were attributed to only lawful conduct); *U.S. Football League*, 842 F.2d at 1369-70, 1377 (plaintiffs' decisions, not defendants conduct, led to injury); *MCI Commcn's Corp. v. AT&T Co.*, 708 F.2d 1081, 1162 (7th Cir. 1982) (plaintiff offered no method to disaggregate effects of lawful and unlawful conduct).

5. Plaintiffs Have Adequately Accounted for Various Post-February 14, 2014 Events; Neither Judge Sweet's Injunction Nor Forest's Tainted Communications Campaign Undid the Effects of the Hard Switch

Defendants argue that Judge Sweet's injunction somehow removed the anticompetitive effects of the hard switch tactics. Not so. Forest engaged in a months-long, sustained communications blitz, repeatedly informing doctors, caregivers, and other market participants of the impending removal of Namenda IR. PASoF ¶¶350-52; PRSoF ¶¶398, 484, 489. While the injunction required Forest to communicate that Namenda IR would remain on the market, its post-

injunction communications were not nearly as pervasive or repetitive as the months-long campaign to "over-communicat[e]" the hard switch (to borrow Forest's phrase). PRSoF ¶¶398, 484, 489. Forest also limited its post-injunction communications to those entities that had received the February 14, 2014 announcement; this effort was not designed to include those who otherwise were informed of the impending withdrawal, whether by the multiple millions of emails and letters or the months of visits to physicians' offices by Forest's representatives. PRSoF ¶398.

In addition, the post-injunction communications campaign merely continued the uncertainty as to the continued availability of Namenda IR. Even before the injunction was entered, Forest announced it would appeal, then announced it was "optimistic" the injunction would be overturned. *See* PRSoF ¶397. When Forest eventually sent communications in January 2015 mentioning the injunction, it often *simultaneously announced that Forest was appealing (challenging) it.* *See* PASoF ¶¶373-384; PRSoF ¶¶397-99, 484. Defendants' economist, Dr. Pierre-Yves Cremieux, [redacted]." PRSoF ¶397. And Forest cites no evidence it engaged in a communications campaign after losing its appeal in May 2015.

Moreover, the injunction prohibiting the removal of Namenda IR did not switch back those who had already converted to the new formulation or demonstrably influence physicians' prescribing habits that were improperly impacted by the hard switch strategy. As Forest noted when planning its switch campaign, "[redacted]." PRSoF ¶412. Thus, once physicians began prescribing Namenda XR, absent a compelling reason to do so, they would be slow to switch back to Namenda IR. PRSoF ¶¶472, 473. Judge Sweet similarly found that physicians would be unlikely to convert patients back to Namenda IR once converted.

PRSoF ¶¶361, 478. All of this evidence, at minimum, creates a genuine issue of material fact as to whether direct purchasers continued to purchase Namenda XR in volumes (and prices) above what they would have in the but-for world.

The supply shortage in the summer of 2014 is of no moment. Dr. Lamb accounted for the supply shortage in his structural break test (O'Shaughnessy Decl. Ex. 56, Lamb Reply ¶50), and even accounting for it, the XR conversion rate is higher after the February 2014 announcement. Notably, [redacted] PRSoF ¶412, belying any notion that reverse commuting was a feasible long-term effect. Defendants again wrongly focus on whether "individuals" might have switched back (Def. Br. at 62), but as Dr. Lamb observed, the correct focus remains on "market transactions, not patient prescriptions[.]" Litvin Decl. Ex. 487, Lamb (Oct. 6) Dep. at 186:7-17. *See also id.* 186:7-188:13.

IV. CONCLUSION

For any or all of the foregoing reasons, summary judgment should be denied.

Dated: December 11, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2017, I served the foregoing on counsel of record via email.

Respectfully submitted,

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